



KPMG Peat Marwick

POLICY ECONOMICS GROUP

**ISSUES RELATED TO THE FEDERAL GOVERNMENT
DRUG PAYMENT POLICIES IN
THE REFORMED HEALTH CARE ENVIRONMENT**

FINAL REPORT





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FINAL REPORT

Principal Investigator: DAVID J. GROSS, Ph.D.

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Project Director: Kathryn Langwell

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Jay Bae, Ph.D. , Project Officer

6325 Security Boulevard

Baltimore, MD 21207

Submitted by:

KPMG Peat Marwick LLP

Policy Economics Group

2001 M Street, N.W.

Washington, DC 20036

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EXECUTIVE SUMMARY

The impact of federal prescription drug pricing policies on the pharmaceutical market is an issue that has been long debated and has gone long unresolved. The federal government has a major role in the market as the largest single payer for prescription drugs (through Medicaid) as well as a large direct purchaser of drugs (through VA and DoD programs). In addition, the federal government has over the years considered a number of policies that would expand access to prescription drugs or restrict the way that prices and reimbursements are set for both public and private sector prescription drug purchases. The debate on comprehensive health reform increased the importance of understanding the impact federal prescription drug pricing issues. Even in the absence of federally legislated health reform, it is important to realize that the federal government's drug payment policies can affect the types of reforms that are being driven by managed care in the private sector, and can have an impact on the operation of competitive forces in the pharmaceutical sector.

The evaluation of federal drug payment policies requires a recognition that the federal government has different and often conflicting concerns that influence its choices of prescription drug payment policies. These concerns include:

- containing costs of drug benefit programs, including Medicaid, Department of Defense programs, and veterans' drug benefits
- expanding access to drug therapies by increasing levels of prescription drug coverage (which are much lower than for hospital care and physician services) and by increasing consumer affordability of prescription drugs
- promoting competitive forces in the pharmaceutical sector, and minimizing the impact of federal drug payment policies in hindering the effectiveness of private drug cost containment efforts, and
- encouraging the development of cost effective new products and promoting an atmosphere in which prescription drug manufacturers can maintain their world leadership in the pharmaceutical research and development.

In issuing its request for this study, the Office of Research and Demonstrations (ORD) of the Health Care Financing Administration (HCFA) noted the absence of a conceptual framework for evaluating the impact of federal drug payment policies on the pharmaceutical market. Most of the economics and policy literature on the effects of federal drug payment policy focuses on a particular element of the prescription drug sector. Although federally-driven comprehensive health reform is no longer on the immediate policy agenda, the importance of analyzing these factors within a single framework has not diminished. Current federal prescription drug payment policies, as

well as any that might be considered in the future, will affect a market that is currently undergoing major changes.

The Office of Research and Demonstrations of the Health Care Financing Administration contracted with the Policy Economics Group of KPMG Peat Marwick to: (1) conduct a comprehensive study of work pertinent to Federal Government drug payment policies; (2) develop a theoretical model of the prescription drug market, capturing the effects of Federal Government drug payment policies on the overall market for prescription drugs; and (3) assess the appropriateness of current or alternative mechanisms for prescription drug payment, including an analysis of various economic incentives that current and proposed policies and drug benefits create for different players in the prescription drug market.

Background

Legislative History of Prescription Drug Payment Policies

While federal involvement in the regulation of prescription drugs dates back to the 1938 (with the passage of the Federal Food, Drug and Cosmetic Act), the federal government took no direct role in drug pricing and reimbursement until the 1960s. The first federal prescription drug benefit was implemented through the Medicaid program which, since its 1965 inception, has included prescription drug coverage as an optional benefit for states. In 1967, 37 states included prescription drug coverage for Medicaid beneficiaries. This number has gradually increased so that, by 1992, all state Medicaid programs had some type of outpatient drug benefits (Gondek, 1994).

In contrast to its role in Medicaid, outpatient prescription drug coverage was not originally part of the Medicare program. Several efforts were made to include this benefit in the years following the introduction of Medicare. In 1968, President Johnson's Task Force on Prescription Drugs recommended the incremental adoption of a Medicare outpatient prescription drug benefit (Kudrle and Lennox, 1980). However, the Task Force's recommendations were not adopted; nor was a 1972 effort to add a similar drug benefit.

During the 1970s, Congress considered several comprehensive health reform and national health insurance proposals which would have increased access to prescription drugs. Three major bills considered in the mid-1970s--the 1974 Nixon-Ford Comprehensive Health Insurance Plan (CHIP), the 1974 Comprehensive National Health Insurance (Kennedy-Mills) Act, and the 1976 Health Security (Kennedy-Corman) Act--all included prescription drug coverage. However, prescription drug coverage was far less generous in the comprehensive reform proposals that were considered in the late 1970s. The Health Care for All Americans (Kennedy-Waxman) Act of 1979 included a drug benefit only for elderly people suffering from chronic illnesses. President Carter's proposed National Health Plan included no prescription drug benefits.

Along with efforts to expand access, the 1970s also saw the first federal efforts to restrict prescription drug costs in the Medicaid program. The Maximum Allowable Cost/Estimated Acquisition Cost (MAC/EAC), developed in 1975, set the maximum reimbursement limit for purchases under Medicaid at the estimated acquisition cost plus a dispensing fee. The program was designed to ensure reasonable pharmacist profits and encourage low cost substitution.

In the 1980s, prescription drug access and availability were broadened by two major pieces of legislation, one of which was repealed before taking effect. The Orphan Drug Act of 1983 gave drug manufacturers tax credits and exclusive marketing rights as incentives for developing drugs with small patient populations that might not otherwise be profitable. The 1988 passage of the Medicare Catastrophic Coverage Act was the first major expansion of health care benefits passed by Congress since 1965. This legislation added an outpatient prescription drug benefit to the Medicare program, with costs controlled through shared costs (a \$600 deductible in 1991), reimbursement based on average wholesale price, and a computerized drug utilization review system. The prescription drug benefit was scheduled to start in 1990, but the law was repealed in 1989 before implementation.

Federal prescription drug policies in the 1980s and early 1990s focused more on pharmaceutical cost containment initiatives than on expanding prescription drug benefits. In 1984, the Drug Price Competition and Patent Restoration (Waxman-Hatch) Act changed the cost containment focus from regulation to a reliance on market forces by reducing FDA requirements for generic drug approval. Under the Waxman-Hatch Act, generic drug producers no longer needed to prove safety or efficacy to obtain FDA approval, but were required only to show bioequivalence to originator drugs. The regulation also authorized patent life extensions for patented drugs of up to five years to compensate for regulatory delays, with a maximum effective patent life of 14 years.

With the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), the federal government adopted new regulatory cost containment strategies to reduce Medicaid payments to drug manufacturers. OBRA '90 mandated a manufacturer rebate agreement on all Medicaid purchases of prescription drugs. The rebate is based on the best price and the average price charged by drug manufacturers to all customers. Since OBRA '90, these rebates have cost drug companies an estimated \$1.5 billion a year (Guenther, 1994). OBRA '90 also placed limits on state prescription drug payment regulations. It originally banned formularies and prior authorization for newly approved drugs. (These provisions were revoked in OBRA '93.) It also limited states' prior approval response time to 24 hours and required state Medicaid programs to conduct drug utilization review (DUR)..

The Veterans' Health Care Act of 1992 had even stronger discount requirements than OBRA '90. It required that the prices for Veterans' Affairs (VA) and Department of Defense (DoD) contracts be discounted to inflation-adjusted 1990 levels. Manufacturers

were encouraged to negotiate new contracts at lower prices. These requirements assured the VA and DoD would pay the lowest price charged by drug manufacturers to any customer, and were projected to save the VA and DoD \$570 million in 1993 (Guenther, 1994).

Issues of expanding prescription drug benefits and instituting cost controls returned to the policy agenda with the 1992 election of President Clinton, and his Administration's early emphasis on comprehensive health insurance reform. President Clinton's 1994 Health Security Act proposed standard health benefit plans that included coverage for outpatient drugs and biological products (e.g. insulin). In addition, the Act included the addition of the outpatient drug benefit to Medicare. Medicare drug reimbursement would be similar to reimbursement under Medicaid, including the use of drug rebates (although the rebates would differ slightly from those applied to Medicaid). The Administration plan also would have created an Advisory Council on Breakthrough Drugs. The Council could not set prices, but would evaluate the "reasonableness" of prices on new drugs and report them publicly. It was envisioned that the Council could help raise public pressure on manufacturers who were judged to be changing excessive prices.

According to CBO estimates, out-of-pocket expenditures on prescription drugs under the Administration plan would have dropped from about 50 percent to 20 percent of total costs. Total expenditures would have increased by between 5 and 7 percent, and manufacturer profitability would increase by about 3 percent. The Medicare prescription drug benefit would cost an estimated \$66 billion between 1995-2000 (O'Sullivan, 1994). Total R&D investment would not be greatly affected, but the focus of R&D efforts would switch from older age group illnesses to younger age group ailments (CBO, 1994).

Modifications of the Administration plan, as well as a number of alternatives, were also introduced. Some, such as the Gephardt bill (H.R. 3600) and the Mitchell bill (S. 2357) included generous prescription drug benefits, although under a slightly different financing framework than that proposed by the administration. Others, such as Senator Dole's small group insurance reform proposal (S. 2374), the Chafee-Breaux (Senate Mainstream Coalition) plan, and the McDermott single payer bill (H.R. 1200) would have used vastly different approaches for expanding access to prescription drug benefit. In the end, none of these proposals were enacted.

Literature on the Impacts of Drug Reimbursement Policies

The model of the pharmaceutical industry developed under this project is based in part on a review of the literature on prescription drug payment policies. The policies reviewed include those adopted in this country by private payers, the federal government, state government programs, and foreign countries with national health insurance systems. The literature focuses on four types of policies: patient based approaches, provider and pharmacy based approaches, manufacturer based approaches, and market based approaches.

Patient based approaches are designed to reduce the cost and inefficiency of a prescription drug benefit by increasing price sensitivity on the part of drug consumers. These approaches include the use of cost sharing (deductibles, co-insurance, and copayments) and prescription limits. Most published analyses of these policies have focused on controls applied by state Medicaid programs. Many of these studies provide results that are not generalizable (Reeder, et al., 1993; Soumerai, et al., 1993). Of those studies that do offer general lessons, the most significant finding is an observation of decreased drug utilization even at low levels of copayments. The converse--specifically, the provision of prescription drug coverage--was observed by Stuart, et al. (1994) to induce utilization for elderly consumers who would not use prescription drugs in the absence of such coverage. In addition, there is some evidence that the decrease in drug utilization associated with cost sharing may increase the use of other health services (Reeder, et al., 1993; Soumerai, et al., 1993). However, the long term consequences of cost sharing are not well understood.

Little is known about the appropriateness of patient based approaches with respect to their impact on the quality of health care--specifically for low income groups--nor at what level utilization drops for essential drugs rather than for nonessential products. Negative impacts have been documented by Reeder and Nelson (1985) and Soumerai, et al. (1987), each of whom observed reductions in the use of both essential and non-essential drugs when a Medicaid copayment was introduced. Reeder, et al. also noted the uncertainty regarding the relationship between increases in cost sharing on pharmaceuticals and the utilization of other drugs or other health services. Prescription drug limits on elderly Medicaid beneficiaries were observed to reduce prescriptions per patient, but had implications for the health of at-risk patients and increased the likelihood of nursing home admissions.

Provider and pharmacy based approaches, such as formularies, prescribing budgets, drug utilization review (DUR), and limits on dispensing fees, are intended to control prescription drug expenses by increasing the cost awareness of physicians and pharmacists or by direct intervention in their decision making processes. These types of policies have been adopted to different extents by private insurers, the Medicaid program, and other countries' social insurance systems. The literature is divided on the effectiveness of these policies. For example, critics of DUR suggest that its costs outweigh its benefits (Soumerai and Lipton, 1995) and that there is little or no evidence that DUR is an effective cost containment tool (Smalley, et al., 1995). Others conclude that DUR programs are productive and efficient (see, for example, Kralewski, et al., 1994). The literature on the impacts of drug formularies is similarly inconclusive. One reason is that formularies, which are used by some hospitals, managed care organizations, and state Medicaid programs to deny reimbursement for certain drugs or to encourage the use of other drugs, differ from one another in the degree to which restrictions are applied. In addition, many of the studies of formularies' effects do not adequately control for intervening factors (Soumerai, et al., 1993). Other studies differ on whether formularies reduce per capita drug spending, increase non-pharmaceutical spending, and on the extent

to which they restrict or delay access to important drugs. Literature on prescription drug budgets, largely limited to the 1993 adoption of drug budgets in Germany, have found a shift towards the use lower-priced generic drugs and a reduction in drug utilization (mostly for products deemed to be of questionable therapeutic effectiveness). However, the long term effects cannot yet be evaluated.

Manufacturer based approaches applied by the government include rebates, price review boards, and price and profit regulations. Rebates have been applied in the Medicaid system since 1990, and were part of the Clinton Administration's Medicare drug benefit proposal. Under the current Medicaid rebate, for example, the rebate is based on the average price charged by the manufacturer to all customers. The Medicaid rebate appeared to cause a leveling of per capita Medicaid drug expenditures during its first three years of operation (Schondelmeyer, et al., 1995). However, because the rebate amount is based on the price charged to private buyers, manufacturers can reduce its cost by reducing discounts given to private sector customers. According to studies by the U.S. General Accounting Office, this pattern seemed to be occurring in the first two years following imposition of the Medicaid rebate (GAO 1993a; GAO 1994b). Similar results were obtained in an analysis of a rebate on generic drugs as part of a Medicare drug benefit (KPMG Peat Marwick, 1994).

Price review boards, price controls, and profit controls have been applied in other countries to restrain the cost of a prescription drug benefit; reimbursement limits have also been used in other countries and this country's Medicaid system. In Canada, a price review board on patented drugs was found to be effective at restraining price increases, but may not have been effective at restraining new drug prices (GAO, 1993b). European experience with direct price controls suggests that such policies are not effective at controlling spending growth, because they do not affect levels of drug utilization (GAO, 1994a; Redwood, 1993). Furthermore, these policies may have adverse impacts on pharmaceutical R&D, although the effects of such policies are difficult to ascertain. Countries with higher drug prices have more development of drugs that are sold globally (Redwood, 1993; Thomas, 1993), but prices are not the only determinant of pharmaceutical R&D (GAO, 1994a).

Market based approaches for prescription drug reimbursement include promotion of generic competition, use of managed care approaches, and applying cost effectiveness analyses to determine drug value. The 1984 Waxman-Hatch Act, which simplified the process by which generic drugs are approved by the Food and Drug Administration, resulted in greatly expanded access to lower priced generic drugs. Generic drug utilization has risen from about 15 percent of the market (in terms of number of prescriptions) in 1983 to 40 percent in 1993 (Boston Consulting Group, 1993). The growing trend of managing pharmacy benefits, be it through hospitals, HMOs, direct third-party payer actions, or pharmacy benefits managers, has promoted use of generic drugs as well as greater competition between therapeutically similar innovative products. These organizations create incentives for providers and patients to use less expensive or

more cost effective drugs. While these approaches seem to be effective in reducing costs of a drug benefit, questions have been raised about their impact on quality of care.

Outside of the United States, governments with social insurance systems have used approaches such as limiting the drug reimbursement rate to the price of a generic product or a less expensive therapeutic alternative (Gross, et al., 1994; Redwood, 1994). The use of cost effectiveness analysis has been growing among both private insurers and in public health insurance systems. In Australia, new drugs must provide cost effectiveness information in order to qualify for reimbursement under the national health insurance system. Cost effective criteria are also being considered in Canada and other countries, although a number of methodological problems inherent in performing cost effectiveness studies are still unresolved.

Theoretical Model of the Pharmaceutical Market

A theoretical model of the pharmaceutical market that can be used to analyze the impact of various prescription drug payment reforms is developed in this study. This model incorporates the concept of a pharmaceutical industry with several components: multi-firm drug manufacturers that operate as price discriminating monopolists, charging different prices to different market segments; generic drug manufacturers that operate in a mode which is closer to perfect competition than to monopoly; consumers who purchase drugs from retail pharmacies; institutional buyers that are able to negotiate lower prices for drugs; and government as a payer of drugs. The model provides a tool for examining the impact of a wide variety of federal drug payment policies on different products sold by a single firm; on different types of firms; on different types of consumers; and on the level of competitiveness within the market. It also provides the opportunity to conduct a short- and long-run analyses of policy impacts. The behavioral assumptions for the model are based on the existing literature on pharmaceutical industry. This literature is summarized in the main report.

The model is developed sequentially. First, the model of the *multi-product firm* is presented, reflecting typical characteristics of pharmaceutical manufacturers that set them apart from other types of companies. This component sets up a dynamic framework under which it is possible to observe the effect of entry into and exit from different product lines. The model of the pharmaceutical manufacturer is adapted from Cocks (1992), who in turn applied Clemens' (1958) model of the multi-product firm to the pharmaceutical industry. This approach is a Schumpeterian model of the pharmaceutical manufacturer, in that it emphasizes change in the market and the manufacturer's adaptation to that change. The model is a dynamic one, in which the market never reaches equilibrium. Rather, it allows for continuous decisions by the pharmaceutical firm that are a result of the firm's research and development activities; other firms' entry in certain product lines; and changes in the nature of the demand for prescription drugs.

The model incorporates a number of assumptions about prescription drug manufacturers and the markets in which they operate. Consumers or their agents are

assumed to be price sensitive (although the degree of price sensitivity will vary with levels of insurance coverage and on the practices of each insurer). Drug manufacturers are assumed to be profit-maximizing firms that sell multiple products. It is assumed that firms use similar production processes for different products; for example, that manufacturing facilities can be used for the production of different medicines (subject to FDA regulatory oversight), and that research scientists can be shifted from one to another related R&D project. It is assumed that resources are easily transferable within the firm at least in the medium and long term. R&D is assumed to be the primary catalyst for changes in the portfolio of drugs produced by each firm.

In the short run, each firm's marginal costs are assumed to be a low share of total costs and are assumed to be constant over the relevant range of output, reflecting the fact that many of the costs incurred in drug development (such as R&D and marketing) do not change with the quantity of the product purchased. In the long run, however, all drug manufacturing costs are variable.

Market conditions for the various products manufactured by each firm can range from strong market power--for products for which no therapeutic substitute exists--to pure competition for products with a large number of competitors. In between these extremes are different levels of competition that are affected by the number of generic and non-generic substitutes for a product, and the willingness of drug consumers or their agents to substitute between one product and another.

Firms are assumed to enter new markets in order of their expected profitability. Each firm also tries to enhance the profitability of its products by attempting to establish a unique therapeutic niche for those products--separating each in some way from the products produced by competitors. The firms try to maximize profitability over time by dedicating sufficient resources to R&D to maximize the chance of developing pioneer products that bring the most profitability to the firm.

Second, the model is extended to show the *dynamics of a multi-firm industry*, with different types of manufacturers. While the single-firm model allows us to examine the dynamics of a changing market on one firm, this extension can be used to simultaneously compare the impacts of policies on several firms. Within this multi-firm context, the actions of one firm can affect another firm. For example, the introduction of a competitor to an originator product will both reduce demand for that product and, potentially, change the slope of the demand curve. The introduction of a generic drug will have a more severe impact on an innovative manufacturer, leaving it with a much smaller market share and with a more price insensitive segment of the market.

Third, the model is extended to allow manufacturers to *segment their markets* to different types of buyers. The ability to show segmented markets allows the model to be used to examine the impact of government drug payment policies on both the retail class of trade and the institutional class (where managed care approaches are more likely to be used). The pharmaceutical market satisfies three conditions required for manufacturer

practice of price discrimination: (1) possibilities for reselling drugs are limited; (2) products are not perfectly homogeneous; and (3) sellers can segment the buyers according to their different demands for the product (Berndt, 1994). This third condition is based on the recognition that the demand functions of institutional buyers--such as hospitals, HMOs, pharmacy benefits managers (PBMs), and nursing homes--differs from those who obtain their drugs through the retail class of trade. Institutional buyers have control over the drug distribution network for a large quantity of purchases, as well as a greater knowledge than retail customers of how drugs can substitute for one another. Institutional buyers are therefore more able to negotiate price discounts and rebates from drug manufacturers. Reflecting this ability, the model differentiates the institutional class of trade from the retail class of trade,¹ assuming the demand by institutional buyers to be more price elastic than the demand by the retail class of trade.

Finally, the model includes an R&D component that is used to evaluate the impact of drug payment policies on manufacturer R&D decisions. This component separates R&D efforts into those activities that cannot be ascribed to any particular product, and those that involve applying research to the development of known drugs. The subcomponent on general R&D activities assumes that manufacturers require a certain return in order for the firm to cover long run costs. Reducing an average rate of return through cost control policies will reduce the ability of firms to engage in these overall research efforts.

The drug-specific R&D subcomponent assumes that the firm can examine the impact of policies on different types of drugs (e.g. those that offer substantial therapeutic improvements over existing treatment, moderate improvements, or marginal improvements). By assuming that that firms have some broad estimates of lifetime revenues for these drugs (based on both potential market size and an estimated probability of reaching the market) and estimated R&D costs for each drug, different types of policies can be examined in terms of their impacts on each type of drug. When a policy makes the expected return from a drug less than the expected costs, firms are assumed to reevaluate their decisions to produce drugs. Some policies may lead to a reevaluation for all products; some may reduce revenues or raise costs on major therapeutic improvements; and some may maintain returns on major therapeutic improvements but reduce incentives for producing more imitative products.

The model is used to examine the impact of adopting different types of spending control policies in conjunction with the introduction of an expanded prescription drug benefit. The approaches examined include:

- reducing the cost of a drug benefit by lowering average price paid by government programs for prescription drugs (through manufacturer rebates; price controls; drug price review boards; and unitary pricing laws)

¹ For purposes of simplification, it is assumed that the institutional class of trade pays one price, but in reality this price likely varies by buyer.

- reducing the cost of a drug benefit by lowering the level of drug utilization (by increasing patient cost sharing or imposing controls on physicians)
- administering drug benefits through managed care organizations, such as HMOs and PBMs (using approaches applied in the private sector to reduce drug benefit costs and improve efficient drug utilization)

Application of the Model to Examining the Impact of Pricing Regulations on the Pharmaceutical Market

The drug pricing regulations discussed in the report focus on prices charged by drug manufacturers. These prices account for the largest share--about two-thirds--of total prescription drug costs. Policies that restrain the prices that manufacturers charge (and that are sometimes combined with limits on fees that can be charged by pharmacists or other drug distributors) can play a large role in reducing costs to private and public third-party payers as well as to consumers (to the extent that they pay some of the costs of the drugs they use). However, these policies can also have unintended and adverse consequences on the pharmaceutical market. They can reduce incentives for competitors to enter markets that, in the absence of price controls, would have been more profitable; stifle innovation of therapeutic improvements; create a welfare loss; decrease the funds available for pharmaceutical R&D; and shift incentives for engaging in R&D from major therapeutic improvements to more minor improvements or “me-too” drugs.

Drug manufacturer rebates are shown to initially reduce the cost of a Medicaid or Medicare prescription drug benefit, but firms’ reactions to the rebate can result in decreased government savings and higher costs to private payers. The rebate is based on the relationship between the retail price (the price normally paid by Medicare and Medicaid beneficiaries) and the prices charged in the institutional class of trade.² When the rebate is imposed, the net cost to the government will be reduced if the manufacturer does not adjust prices in reaction to a rebate. However, since the rebate effectively raises manufacturer’s marginal costs, firms will raise prices in both the institutional and retail classes of trade. The model shows that action results in a shifting of costs from the manufacturer to private payers, and a reduction in the value of the rebate to the government. In addition to these impacts, a rebate could, at the extreme, reduce competition by leading manufacturers to stop producing marginally profitable products, and slow or inhibit pharmaceutical R&D on such products.

Direct price controls, used in some single-payer or national health insurance systems to establish drug prices, will vary in impact in relation to the severity of the

² For example, the Medicaid rebate on branded drugs is the greater of: (a) 15 percent of the average manufacturer price (AMP) and (b) the difference between the AMP and the lowest, or best, price charged by the manufacturer.

control applied. The model shows how, in the short-run, the introduction of direct price controls has the potential to reduce the cost of a prescription drug benefit. Over time, however, price controls can adversely affect consumers and the pharmaceutical market. First, by reducing the profits that are earned from sales before competitors are on the market, a price control limits the incentives for introducing competing products which can lead to market-driven price reductions and, at times, therapeutic improvements over existing products.³ Second, the lack of competing forces may lead to higher prices than would exist in the absence of regulation. The regulated price may tend to act as a ceiling as much as a floor, and manufacturers of competing products that do choose to enter the market may opt to compete on the basis of perceived quality rather than on cost. To the extent that competition (rather than regulation) causes price reductions, it decreases the welfare loss from that which occurs under price controls. Third, price regulations may affect the profitability of drug manufacturers and their decisions on drug development. The impact on major therapeutic improvements as compared to imitative products depends on the type of control being applied.

Drug price review boards have less severe impacts than direct price controls because they typically are not designed to cover all products and because the boards have limited enforcement powers. Our model suggests that such a board reduces prices charged in the retail class of trade, but will not affect the institutional class of trade if prices in that sector are already below the price set by the board. Pharmaceutical R&D would be adversely affected to the extent that the board is successful in reducing drug prices and manufacturer revenues, but the magnitude of this effect is difficult to determine. Our analysis of a price review board that has jurisdiction only on breakthrough drugs, such as that proposed in the Clinton Administration's health reform proposal, suggests that such a policy has the perverse impact of reducing incentives for developing major therapeutic improvements, but would not reduce the incentives for developing imitative drugs.

Unitary pricing laws, also known as *non-discriminatory pricing laws*, are designed to reduce prices charged in the retail class of trade by restricting the ability of manufacturers to exercise price discrimination to different market segments. While supporters of these laws assert that they would reduce prices charged in the retail sector, our model suggests that retail prices would probably not fall to the level that they are in the institutional class of trade. Rather, the drop in retail prices would be accompanied by an increase in prices charged to the institutional class of trade. The degree to which either of these impacts dominates the other depends on the size of the institutional sector, the power of the institutional sector to obtain discounts, and the degree of competitiveness between products in any particular product line.

Impact of Cost Sharing, Controls on Physicians, and Use of Managed Pharmacy Benefits

³ While some of these latter-entry products are appropriately called "me-too" products, others offer improvements that are beneficial to patients.

Price controls are but one set of policies that the federal government can adopt to expand financial access to prescription drugs. Another approach is to expand coverage through a government drug benefit or through private sector mandated drug coverage. However, this approach is a costly one in that it shifts costs to the insurer and increases the demand for prescription drugs (to the extent that the policy reduces consumer out-of-pocket payments). In reducing the costs of such an approach without resorting to price controls, the federal government could adopt reimbursement policies that encourage beneficiaries and their physicians to make more optimal decisions in the use of prescription drugs. These policies make beneficiaries and providers more conscious of the cost of drugs purchased, and give them incentives to reduce utilization or to reduce the average price of the market basket of drugs consumed. Three types of approaches are examined:

- Cost-Sharing. The first set of policies would increase cost sensitivity by program participants. The imposition of deductibles, copayments, or co-insurance in an expanded prescription drug benefit can reduce program costs and make beneficiaries adopt more efficient drug purchasing practices.
- Physician incentives. The second set of policies is directed at physicians, who make the ultimate decision about drug prescribing. In a fee-for-service reimbursement system--particularly one in which the patient bears little or none of the cost of drugs--there is little incentive for physicians to be concerned with prescription drug prices. However, policies such as spending targets, physician benchmarking, and prescription drug budgets can be applied to make physicians more sensitive to the costs of competing drugs.
- Managed care. The third set of policies relies on external entities--such as managed care organizations and pharmacy benefits managers--to manage prescription drug benefits for Medicare or Medicaid beneficiaries. These organizations can adopt policies used in the private sector to reduce the costs and improve the cost effectiveness of a prescription drug benefit, in return for a capitated fee for each beneficiary.

Three different types of *cost sharing policies* are examined--deductibles, copayments, and co-insurance. These approaches reduce the cost of a prescription drug benefit by shifting costs to consumers and reducing levels of drug utilization. However, each policy differs in the degree of effectiveness and in their impact on the efficiency of drug utilization by individual consumers. For example, deductibles provide no incentive for consumers to seek lower priced drugs (such as generic drugs) or to reduce utilization that may not be medically necessary, and the levels of consumption that might be reduced are those that contribute the highest levels of utility. In contrast to deductibles, fixed dollar copayments raise prices on all drugs consumed. But, like deductibles, copayments do not necessarily encourage consumers to choose less expensive products unless the

copay is smaller for the less expensive drugs. Co-insurance, which sets a fixed percentage copayment for prescriptions, rewards consumers for choosing less expensive drugs and, unlike deductibles, does not discourage the consumption only of products with high marginal utility. However, if set sufficiently high, both co-insurance and copayments can reduce utilization of necessary drugs, particularly for low income consumers.

In addition to their impacts on individual consumer demand, each of these cost sharing policies will affect returns to drug manufacturers and funds available for drug development to the extent that they reduce returns to manufacturers. However, it is difficult to determine whether these impacts are of sufficient magnitude to affect drug manufacturer's decisions, particularly if the policies are implemented in conjunction with a drug benefit that increases demand for drugs (such as a Medicare prescription drug benefit).

Spending control policies aimed at *physicians*, such as providing educational information, adopting spending targets, and instituting drug budgets, are also examined. These policies can affect prescription drug spending in two ways. First, they may lead physicians to reduce prescriptions of drugs that are not medically necessary. Second, they may encourage physicians to change the mix of drugs that they prescribe to products that are less costly, including both generic drugs and lower-cost patented products. The model shows that these practices will encourage pricing competition between therapeutically similar products and reduce utilization of drug with little therapeutic value, with the magnitude depending on the rigor with which they are applied. While these approaches could, potentially, restrict patient access to necessary drugs, there is little evidence that such restrictions occur.⁴

Adoption of *external management of pharmacy benefits* for a publicly-funded drug benefit shifts the financial risk and responsibility for cost control to outside entities. This approach, which provides managed care organizations with a capitated payment for providing prescription drugs, can promote the operation of competitive forces in the administration of a prescription drug benefit. Price competition between products will be enhanced, as will the use of cost effectiveness approaches. Returns to pharmaceutical manufacturers would likely be lower under a fee-for-service system, but would increase the return to innovative product with few substitutes relative to imitative products with many competitors. In addition, it will provide greater returns to manufacturers that can successfully operate in a competitive environment. However, it is possible that managed care organizations will try to reduce costs by restricting patient access to drugs which patients may desire or require. Patients may find that these restrictions reduce the quality of care they are receiving, and may feel that these restrictions reduce access at the expense of care.

⁴ For example, despite concerns that adoption of a physician drug budget in Germany would decrease access to important drugs, German government statistics show that the bulk of the reductions have been applied to these therapeutically questionable drugs (GAO, 1994c)

Issues in Designing an Optimal Drug Payment Policy

The framework developed in this study provides a context for examining the impact of federal drug payment policies on the various aspects of the pharmaceutical market. The model offers a number of advantages over the existing literature. It allows us to examine short- and long-run impacts of federal prescription drug payment policies; provides a context for simultaneously analyzing these impacts on the different products in a manufacturer's portfolio; examines the different impacts of policies on the retail and institutional classes of trade; and isolates the impact of policies between the innovative and generic drug industries. The model can be applied to comprehensive reforms, such as the universal coverage proposals that were considered in the 103d Congress, as well as to incremental reforms that are currently being considered.

The analysis that emerges from this model suggests that there is no optimal prescription drug policy, *per se*. Rather, evaluation of each policy option requires the consideration of tradeoffs between expanding financial access and increasing market efficiency. This complexity reflects the conflict between the different and conflicting government roles in the pharmaceutical sector. For example, the federal government's interest in pharmaceutical cost control runs counter with its desire to have a strong pharmaceutical industry. On the one hand, the government has a commitment to providing prescription drugs to those populations for which it provides benefits and, according to some government officials, preserving affordable prescription drug prices in the private market. However, policies used to achieve these goals may reduce revenues to drug manufacturers. This revenue loss may reduce the ability of manufacturers to engage in the types of activities that provide substantial employment, contribute to a reduce trade deficit, and result in new live-saving or life-improving drug products. Furthermore, the policies could inhibit competitive forces that, by themselves, can bring down drug costs while providing incentives for continued drug development. By contrast, however, policies that allow the pharmaceutical market to operate freely result in high prices, high program costs, and reduced financial access to prescription drugs.

One of the first conclusions of our analysis is that drug reimbursement policies that focus primarily on increasing short-term access to prescription drugs can indeed do harm to competitive forces and future drug development. For example, tightly applied price controls can reduce the costs of prescription drugs to both consumers and payers, but can adversely affect competitive forces in the pharmaceutical industry. Specifically, the price controls limit incentives for payers such as MCOs and PBMs to develop more efficient prescription drug benefit programs. The price controls also distort the rewards faced by drug manufacturers for evaluating between innovative and imitative drug development. In addition, price controls inhibit cost-effectiveness in medical treatment because they do not lead providers to recognize the *economic price* of the products, but instead promote the use of products that are less cost effective but that have a lower *financial price*.

A second set of lessons from the analysis relates to the use of policies that are intended to increase consumer and physician sensitivity to drug prices. While such policies can lower the cost of a prescription drug benefit and reduce inefficient consumption of prescription drugs, they can sometimes reduce consumer access to necessary prescription drugs. The imposition of deductibles, copayments, or coinsurance makes consumers more aware of drug costs, but can reduce financial access to prescription drugs, particularly for low income households. In addition, the incentives for efficient drug utilization associated with deductibles and copayments may actually promote inefficient levels of consumption. The adoption of physician benchmarking and physician drug budgets has reduced prescription drug benefit costs and has shifted consumption towards less expensive therapeutic substitutes. However, these policies emphasize prescription costs over total treatment costs or patient outcomes. As a result, they have the potential to reduce consumer access to drugs that, while being more expensive, are also more effective or may reduce costs of other health services. In addition, a very tight budget may reduce patient access to medically necessary drugs. It is important to note that these issues are important to consider, but that there is no hard evidence on the extent to which this reduced access would occur.

A third lesson from the analysis is that any successful cost control policy will necessarily reduce drug manufacturer revenues and, presumably, the funds available for pharmaceutical R&D. It is not clear of the extent to which any of these policies will affect pharmaceutical R&D, the distribution of revenue losses between different types of manufacturers, or whether drug manufacturers will adjust other costs in order to maintain a strong R&D effort. To the extent that R&D is reduced, some of the approaches would R&D on all products, while others may have a greater influence on the incentives for developing major therapeutic improvements as opposed to imitative medicines (and vice versa). While the direction of these impacts is clear, the magnitude is not. It is not even clear which policies will have a nontrivial affect on drug manufacturer R&D decisions. Such analysis requires further study.

Finally, most of the approaches discussed in this study place a greater emphasis on drug cost than on drug cost-effectiveness. With one exception, the payment policy options we examined focus on prescription drug costs in isolation of the costs of other types of health services. Yet prescription drugs are used in conjunction with physician services, hospital care, as well as other components of health services. Their effective use may lead to cost reductions in these other areas, as well as in better value or improved outcomes for patients. The absence of consideration of cost-effectiveness may infer cost savings for prescription drugs that lead to overall health cost increases or less effective medical care.

The one example in our analysis that allows consideration of cost-effectiveness of drugs is the use of managed pharmacy benefits. Because managed care organizations receive a capitated payment for the provision and financing of a wide range of health care services--often including prescription drugs--they have a financial incentive to develop cost-effective ways for providing that care. Managed care organizations also have

additional advantages over types of reimbursement policies. They often have policies in place to promote cost sensitivity by physicians and patients; they promote price competition by manufacturers; and they can develop innovative purchasing arrangements with manufacturers that can add value to both the payer and the manufacturer of drugs. However, the restrictions that these organizations sometimes place on product availability can be seen as restricting access to drugs by patients and physicians. Whether this lack of access affects the quality of medical care provided has yet to be determined.

The analysis thus suggests that an optimal policy must reflect the relative weights that society puts on each of these components. When society puts the greatest emphasis on low drug costs, it incurs the cost of market inefficiency and less drug development in the long run. When society emphasizes the need of drug manufacturers to earn high returns in order to finance product development, it does so at the cost of higher drug prices and reduced access to prescription drugs. An emphasis by society on market efficiency and cost-effectiveness through the increased use of managed care in the pharmaceutical sector can result in innovative, competitive approaches between payers and providers, but could restrict choices of drugs available to consumers and physicians. By contrast, if society wants people to have access to prescription drugs no matter what the cost, it runs the risk of fiscal pressures resulting from a drug benefit program in which prices and utilization are unrestricted. The resolution of these issues should be made in the political arena rather than in the writings of policy analysts. The best that can be done in the analytical arena is to give policy makers the best possible information about the impacts of the options they consider.

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CHAPTER 1

INTRODUCTION

The impact of federal prescription drug pricing policies on the pharmaceutical market is an issue that has been long debated and has gone long unresolved. The federal government has a major role in the market as the largest single payer for prescription drugs (through Medicaid) as well as a large direct purchaser of drugs (through VA and DoD programs). In addition, the federal government has over the years considered a number of policies that would expand access to prescription drugs or restrict the way that prices and reimbursement are set for both public and private sector prescription drug purchases. Even in the absence of federally legislated health reform, the federal government's drug payment policies can affect the types of reforms that are being driven by managed care in the private sector, and can have an impact on the operation of competitive forces in the pharmaceutical sector.

The evaluation of federal drug payment policies requires a recognition of four different goals of the federal government in this sector: (1) containing program costs; (2) broadening access to drug therapies; (3) promoting the operation of competitive forces in the prescription drug market; and (4) encouraging the development of cost-effective new products. Because specific policies often involve trade-offs among these four goals, the government's task in designing policies that accomplish these goals while avoiding unintended adverse consequences is complex. For example, the government can reduce program costs by increasing consumer cost sharing or placing restrictions on the number of prescriptions a beneficiary may receive each month, but it must then incur the consequences of decreased access for some program participants. Similarly, prescription drug price controls can increase financial access, but may significantly reduce incentives for investment in pharmaceutical research and development (R&D).

Government decisionmakers must also recognize that the impact of any single policy depends on both the market conditions for that product and on the type of product being analyzed. For example, the economic impact of the Medicare rebate proposed in the Clinton Administration's 1994 Health Security Act is likely to be related to the number of generic and non-generic substitutes for the product in question, the product's therapeutic importance, and the leverage that can be exercised by third-party payers. A comprehensive theoretical model is needed to provide a framework for evaluating the impacts of drug payment policy alternatives under the full range of market conditions. In that regard, understanding the rapid and fundamental changes that have been occurring in the pharmaceutical market is central to the conduct of this project.

In issuing its RFP for this study, the Office of Research and Demonstrations (ORD) of the Health Care Financing Administration (HCFA) noted the absence of a conceptual framework for evaluating the impact of federal drug payment policies on the

pharmaceutical market. Indeed, the economics and policy literature has, to this point, lacked a comprehensive framework for evaluating these impacts. Most of the literature on the effects of federal drug payment policy focuses on a particular element of the prescription drug sector. The effects of a policy to expand drug spending and access, for example, is considered without regard to the impact of the policies on drug R&D. Similarly, policies that focus on the factors affecting pharmaceutical R&D do not necessarily reflect the impacts of policies which may favor R&D but hinder financial access to prescription drugs.

Although federally-driven comprehensive health reform is no longer on the immediate policy agenda, the importance of analyzing these factors within a single framework has not diminished. The prescription drug market is undergoing great change, due to the growing presence of managed pharmaceutical care; the altering of the relationships between payers, providers, patients, and pharmaceutical manufacturers and distributors; and vertical and horizontal integration within the pharmaceutical industry. Current federal drug payment policies--particularly those that tie reimbursement in federal programs to the lowest prices charged in the private sector--may adversely affect the competitive operation of the market. Some reforms at the federal level--particularly efforts to increase the use of managed care in the federal Medicaid and Medicare programs--will also change the operation of the market in ways that should be understood. Finally, the political environment can rapidly change, as can be seen by comparing the current Congress to its predecessor. If a future Congress again chooses to consider some of the federal drug payment policies that were examined in the 103d Congress, then it would be important to have in place a framework for examining such policies.

The Federal Role in Prescription Drug Pricing Regulations

As noted above, the federal government has different and often conflicting concerns that influence its choices of prescription drug payment policies. The first of these concerns is to contain costs of its drug benefit programs. The federal government is the nation's largest single payer of prescription drugs. Most of these expenditures take place through the Medicaid program, where all 50 states and the District of Columbia have adopted an optional prescription drug benefit. The federal government also purchases drugs directly in its role as a provider of health care through Department of Defense and veterans' programs. Furthermore, while the federal Medicare program does not have an outpatient prescription drug benefit, it does pay indirectly for inpatient drugs for Medicare beneficiaries through its prospective payment system to hospitals.

The rising costs of providing these prescription drugs has been one element of the fiscal burden facing federally-financed health care programs. Federal Medicaid expenditures on prescription drugs have been rising rapidly over the years, from \$810 million in 1980 to \$4.5 billion in 1993. On a per capita basis, Medicaid drug costs have risen, on average, 9.4 percent annually during the same period.¹ This growth has led to a

¹ KPMG calculations based on Congressional Budget Office data, February 1995.

number of cost control programs, such as limits on drug reimbursements to pharmacies and the 1990 establishment of the Medicaid rebate program, under which drug manufacturers pay back to Medicaid a portion of the revenue from sales to Medicaid beneficiaries. In addition, concern about Medicaid costs led to the consideration of various spending control mechanisms as part of the proposed Medicare prescription drug benefit.

A second concern of the federal government is to expand access to drug therapies. The level of prescription drug coverage in the United States is much lower than for hospital and physician care. This lack of insurance can be a financial barrier to obtaining drug therapies, particularly for the large share of the elderly who do not have a prescription drug benefit.² In addition, those people with prescription drug coverage generally have policies that require a level of cost sharing that is high relative to that required for other health services (Levit, et al., 1994). The efforts to create a Medicare prescription drug benefit (which date back to the 1960s), as well as efforts to provide a drug benefit in a universal insurance program, reflect one approach for increasing access to prescription drugs.

The federal government also has tried to increase financial access by reducing the cost of drugs to all consumers, whether or not they are enrolled in federal health programs. Part of the limitations on drug affordability arises from the increasing average prices of drugs. Congressional concern about drug prices has, to some extent, stemmed from statistics which suggest that prescription drug prices have risen, on average, at triple the rate of inflation during the 1980s and 1990s. While recent evidence has shown that these price indexes have been overstated,³ the perception of excessive drug price increases has led to Congressional investigation of drug price differences in other countries and to considerations for restricting prices that drug manufacturers can charge in this country.⁴

The efforts to restrict federal prescription drug costs may hinder the ability of private sector payers to lower drug costs through efforts to increase the competitiveness of the drug industry. Until recent years, the pharmaceutical industry was one in which price competition among products played a relatively minor role. However, increased sophistication among third-party payers, combined with rising drug expenditures and the greater availability of lower priced generic drugs, has led to the emergence of a number of competitive forces affecting the production and distribution of prescription drugs.

² An estimated 46 percent of the elderly lacked prescription drug coverage in 1991 (Long, 1994).

³ This overstatement arises from three factors. First, prior to 1994 the market basket used to calculate the index under-represented new and recently introduced drugs. Second, the index does not account for cost savings incurred when consumers switch to lower-priced substitutes. Third, the index does not adequately separate pure price changes from those that reflect improved quality. See Berndt, et al. (1993); GAO (1995). In addition, on an inflation-adjusted per capita basis, spending for prescription drugs has risen less than other health spending (CBO, 1994).

⁴ See, for example, GAO (1992); GAO (1994a)

The changing regulatory environment--which allowed lower priced competitors into the market--was one factor affecting competitive forces in the prescription drug market. The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Waxman-Hatch Act) reduced many barriers to the sale of generic drugs. The result was a substantial increase in generic market penetration, from 15 percent of prescriptions in 1984 to almost 40 percent in 1993, and is expected to rise sharply as many popular brand name drugs lose their patent protection.⁵

Another factor that is increasing competition in the marketplace is the increased sophistication of institutional buyers--in particular managed care organizations, hospitals, and nursing homes--in promoting price competition among drug manufacturers. As these payers have become a larger share of the prescription drug market, and as prescription drug prices and utilization have risen, institutional buyers have had strong incentives to adopt cost saving mechanisms. To some extent, their savings reflect a greater reliance on the generic drugs that have become more widely available since the passage of the Waxman-Hatch Act. But these payers have also adopted other measures, such as drug formularies, increased cost sharing, physician education, and approaches for achieving more efficient utilization of drugs. Increasingly, managed care organizations and hospitals are negotiating discounts and risk sharing agreements with drug manufacturers or contracting with pharmacy benefits managers to help them restrain their drug costs. These measures have also led physicians and third-party payers to compare costs of therapeutically similar medicines that, in previous years, did not compete against one another on price, but rather competed on the basis of product differentiation.

Finally, at the same time that the federal government wants to reduce the costs that it and other citizens must pay for drugs, it faces the concern about firms' incentives to continue the development of prescription drugs that will improve health and decrease costs of care. The U.S. pharmaceutical industry has, to date, been the world's leader in the development of innovative prescription drugs. But the high costs of drug development and the high risks associated with the successful development of a new product place a severe financial burden on drug manufacturers trying to develop these new products. The increasing sophistication of buyers in negotiating price reductions is already increasing competitive pressures on drug manufacturers. Any government efforts to restrict the cost of prescription drugs, therefore, has the effect of further reducing the funds available to drug manufacturers for developing products.

Purpose of This Report

The Office of Research and Demonstrations of the Health Care Financing Administration contracted with the Policy Economics Group of KPMG Peat Marwick to:

- conduct a comprehensive study of work pertinent to Federal Government drug payment policies;

⁵ Boston Consulting Group (1993).

- develop a theoretical model of the prescription drug market, capturing the effects of Federal Government drug payment policies on the overall market for prescription drugs;
- assess the appropriateness of implementing current or alternative mechanisms of drug payment, implementing an analysis of various economic incentives that current and proposed policies and drug benefits create for different players in the prescription drug market.

The report is structured as follows:

- The next chapter presents a legislative history of federal involvement in the pricing and reimbursement of prescription drugs. The discussion begins with the 1938 legislative definition of prescription drugs, and proceeds to discussions of expanding prescription drug benefits and cost control efforts from the 1960s to the present.
- Chapter 3 reviews the literature on the impacts of prescription drug reimbursement policies. This discussion examines the evidence on policies that have been applied in the U.S. at the federal and state levels as well as in the private sector. It also reviews evidence of the impacts of prescription drug reimbursement policies that have been applied in other industrialized countries.
- Chapter 4 develops the conceptual model of the pharmaceutical industry that is used in our analysis. This model is based an extension of the model of a multi-product drug manufacturer that was developed by Cocks (1992), which in turn emerges from the work of Clemens (1958). The extension of the model allows us to examine the impact of drug payment policies on different types of drug manufacturers, on the prices charged to different market segments, on the level of competition between drug firms, and on the retail prescription drug sector.
- Chapters 5 and 6 present analyses of the impact of federal drug payment policies using the conceptual model described in Chapter 4. Chapter 5 focuses on policies that directly or indirectly affect prescription drug prices. These include direct price controls, manufacturer rebates, drug price review boards, and unitary pricing laws. Chapter 6 concentrates on policies that are intended to increase awareness of drug costs to consumers, providers, and payers within the context of a federal drug benefit program. The policies analyzed in Chapter 6 include the adoption of cost sharing, physician benchmarking and drug budgets, and the use of managed care organizations or pharmacy benefits managers for providing prescription drug benefits to Medicare and Medicaid beneficiaries.

- The concluding chapter, Chapter 7, summarizes the lessons learned in Chapters 5 and 6, and develops a framework for developing an optimal prescription drug payment policy.

CHAPTER 2

FEDERAL PRESCRIPTION DRUG PAYMENT POLICIES: LEGISLATIVE HISTORY

Federal involvement in the reimbursement and pricing of prescription drugs dates back almost sixty years, to the federal government's role in defining the designation of prescription drugs. Prior to 1938, non-narcotic drugs could be purchased in the United States without a physician prescription. However, the Federal Food, Drug and Cosmetic Act passed in that year, and strengthened in 1951, restricted some drugs from being issued without a physician's prescription. The law also required the federal government to regulate the distribution of those drugs.

At that time, the federal government took no role either in providing direct financing for prescription drug coverage or in regulating prices that could be charged by drug manufacturers. But as prescription drugs have become a more important and more costly component of health care treatment, a wide variety of policies dating to the 1960s have been suggested for both containing prescription drug costs and for expanding financial access to prescription drugs. The following facts illustrate the issues facing prescription drug pricing and reimbursement:

- total annual spending on prescription drugs purchased in retail outlets, per capita, reached \$280 in 1993. This represents more than a 200 percent increase from 1985 per capita spending (Levit, et al., 1993);
- from 1980 to 1993, the reported average inflation rate for prescription drugs was, on average, triple that for the economy as a whole. While this rate is overstated (Berndt, et. al., 1993; GAO, 1995), the perception of high drug prices has driven public policy;
- in its first 25 years, Medicaid expenditures on outpatient drugs rose from about \$182 million to over \$6.8 billion (Colligen, 1993); and
- despite these expenditures, an estimated 72 million Americans still have no coverage for outpatient prescription drugs (Gondek, 1994).

This chapter summarizes major legislative efforts by the federal government to expand access and restrain the cost of prescription drugs. The discussion begins with the institution in 1965 of the Medicare and Medicaid programs, which were followed by national health insurance proposals of the 1970s. This discussion proceeds with a summary of prescription drug cost containment proposals of the 1980s, which focused on

both price limits for Medicaid prescription drug purchases and market-wide enhancement of the availability of generic drugs. The chapter concludes with an extensive discussion of prescription drug coverage and cost control in the 1994 health reform debate.

Increasing Availability

Coverage Under Medicaid and Medicare

The 1965 implementation of Medicare and Medicaid, which represented the first large-scale federal programs to finance health care coverage, did not include coverage for prescription drugs. Prescription drug coverage was an optional benefit for state Medicaid programs, and was not included in Medicare. President Lyndon Johnson created a Task Force on Prescription Drugs to study the pharmaceutical market and assist in the development of a proposal to include outpatient prescription drugs under Medicare. The Task Force issued a report to the Secretary of Health, Education and Welfare (HEW) which recommended such a program, but initially with “less than comprehensive coverage” (Waldo, 1994). It suggested a formulary-based policy which would cover life-saving and life-sustaining drugs for “crippling and life threatening” chronic illnesses (Kudrle and Lennox, 1980). HEW decided against this option and did not include a prescription drug benefit in the Medicare program. In 1972, a subsequent effort to add this benefit to the Medicare program was not enacted.

Decisions on Medicaid benefits and administration were left up to the states’ discretion. In 1967, 37 states included prescription drug coverage for Medicaid beneficiaries. This number has gradually increased over the years. By 1992, Medicaid programs in all 50 states and the District of Columbia had some type of outpatient drug benefits (Gondek, 1994).

Comprehensive Coverage Plans in the 1970s

During the 1970s, Congress considered several comprehensive health reform and national health insurance proposals which would have increased access to prescription drugs. In 1974, there were two competing federal comprehensive health insurance proposals: the Nixon-Ford Comprehensive Health Insurance Plan (CHIP), and the Comprehensive National Health Insurance (Kennedy-Mills) Act. CHIP was based on an employer mandate for insurance coverage and government-provided insurance for the elderly and indigent. It set no limit on prescription drug coverage and allowed the Secretary of HEW to decide on non-prescription, “life-sustaining” drugs (e.g. insulin) to be included in minimum standards. CHIP relied on reimbursement limits (MACs) and cost-sharing (co-insurance and a deductible) to control federal expenditures. The Kennedy-Mills proposal would have abolished Medicaid and created a new government sponsored insurance for those not covered by Medicare. A Formulary Committee would select certain drugs for chronic illnesses which would be covered under the both Medicare and the overall federal plan. Both bills died without action being taken.

In 1976, the Health Security (Kennedy-Corman) Act was proposed. Kennedy-Corman was similar to the 1974 Kennedy-Mills bill, except that it would have put Medicare into a single universal health insurance program. It also would have eliminated the cost-sharing aspects of the original bill.

The end of the 1970s saw two additional efforts at health care reform, but neither act provided substantial increases in access for prescription drugs. The Health Care for All Americans (Kennedy-Waxman) Act of 1979 included a prescription drug benefit for elderly people suffering from chronic illnesses. The Carter National Health Plan of 1979 did not include outpatient drug benefits.

Orphan Drug Legislation

The Orphan Drug Act of 1983 was one of two major pieces of legislation directly aimed at increasing access to prescription drugs. The Orphan Drug Act of 1983 tried to expand patient access to drugs with small patient populations. The Act created incentives for manufacturers to develop these “orphan” drugs which might not otherwise be profitable. The incentives included tax credits up to 50% of the R&D costs and exclusive marketing rights to the drug for up to seven years. Some critics have charged that the latter clause has made it possible for orphan drug manufacturers to charge excessive prices and earn monopoly profits. In 1993, several amending bills were proposed to limit this monopoly. The Stark bill would have levied a “windfall profit tax” on “excessively profitable” orphan drugs. Other bills would have placed limits on the exclusivity and population size clauses.

Medicare Catastrophic Coverage

The 1988 passage of the Medicare Catastrophic Coverage Act was the first major expansion of health care benefits passed by Congress since 1965. Among the elements of this legislation was adding an outpatient prescription drug benefit to the Medicare program. In order to reduce the expected high costs of this new benefit, the legislation outlined several cost containment mechanisms for the new program. These included shared costs (a \$600 deductible in 1991), reimbursement based on average wholesale price (AWP), and a computerized, point-of-sale, prospective drug utilization review system. The Act also requested that the Department of Health and Human Services (HHS) develop and implement a utilization education program for physicians. The prescription drug benefit was scheduled to start in 1990, but the law was repealed in 1989 before implementation. The 1980s ended with no federal coverage of outpatient drugs except for Medicaid programs.

Cost Containment

Three factors--growing pharmaceutical budgets for Medicaid, increasing pharmaceutical prices in the 1980s, and additional efforts to provide a universal prescription drug benefit in the face of high drug costs-- have increased the focus on

federal efforts at pharmaceutical cost containment. Until the 1980s, most of the focus on growing drug costs was at the state level. Among cost control strategies used by states were formularies, prior approval, spending limits, and DUR. With the support of the American Pharmaceutical Association, many states began removing anti-substitution laws that had been enacted in the 1940s and 50s. These laws, which were originally developed to prevent low quality “bootleg” and “counterfeit” drugs, were considered outdated and an obstruction to free market competition. Their removal made it easier for patients to obtain lower priced generic copies of originator drugs.

Reimbursement Limits

The only major federal action to control costs during the 1970s was the initiation of the Maximum Allowable Cost/Estimated Acquisition Cost (MAC/EAC) program in 1975. This program, developed by HEW, set the maximum reimbursement limit for purchases under Medicaid at the estimated acquisition cost plus a dispensing fee. The program was designed to ensure reasonable pharmacist profits and encourage low cost substitution. Many pharmacists, concerned with generic substitution, raised issues of quality and personal liability.

Increased Generic Substitution

In 1984, the Drug Price Competition and Patent Restoration (Waxman-Hatch) Act changed the cost containment focus from regulation to market forces as it lessened FDA requirements for generic drugs. Under the Waxman-Hatch Act, generic drug producers no longer needed to prove safety or efficacy to obtain FDA approval, but are required only to show bioequivalence to originator drugs. The regulation also authorized patent life extensions for patented drugs of up to five years to compensate for regulatory delays, with a maximum effective patent life of 14 years. The effect of this law has been a dramatic growth of the generic drug industry. From 1983 to 1993, the generic share of the market (in terms of number of prescriptions) rose from about 15 percent to almost 40 percent, and is expected to continue increasing as many popular brand name drugs lose patent protection (Boston Consulting Group, 1993).

Rebate and Discount Requirements

With the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), the federal government adopted new cost containment strategies to reduce its payments to drug manufacturers. OBRA '90 mandated a manufacturer rebate agreement on all Medicaid purchases. The rebate on single-source drugs was originally set at 12.5 percent of the average manufacturer's price (AMP) *or* the difference between the AMP and the “best price” offered (that is, the lowest priced charged by drug manufacturers to any customer). The requirement for multiple-source drugs was 10 percent of AMP. The rebate was designed to ensure that the government was a “prudent purchaser” of prescription drugs. Since OBRA '90, these rebates have cost drug companies an estimated \$1.5 billion a year (Guenther, 1994).

OBRA '90 also placed limits on state prescription drug payment regulations. It originally banned formularies and prior authorization formularies for newly approved drugs. (These provisions were revoked in OBRA '93.) It also limited states' prior approval response time to 24 hours and required state Medicaid programs to conduct DUR.

The Veterans' Health Care Act of 1992 had even stronger discount requirements than OBRA '90. It required that the prices for Veterans' Affairs (VA) and Department of Defense (DoD) contracts be discounted to inflation-adjusted 1990 levels. Manufacturers were encouraged to negotiate new contracts at lower prices. These requirements assured the VA and DoD of "best price" contracts; that is, the lowest price charged by drug manufacturers to any customer. The law also raised the Medicaid rebate level to 15.4%. The new discounts were projected to save the VA and DoD \$570 million in 1993 (Guenther, 1994).

Comprehensive Health Reform Revisited: 1993-94

With the election of President Clinton, comprehensive health insurance reform emerged once more on the national agenda. Issues of drug prices, budgets, access, quality and innovation took on renewed interest and concern. New proposals were developed to address the issues of access and cost containment with respect to prescription drugs.

President Clinton's Health Security Act proposed standard health benefit plans that included coverage for outpatient drugs and biological products (e.g. insulin). The Administration plan, which would have guaranteed universal insurance coverage, was based on a managed-competition "regional health alliance" system. The alliances would have acted as insurance purchasing cooperatives, pooling risk and using bargaining power to negotiate low prices. Premium growth for the alliances would have been capped at inflation.

Standard benefit packages under the Administration plan would have offered four options: a low cost sharing (HMO style) plan, a high cost sharing (fee-for-service) plan, a combination plan and Medicare. Recipients of Medicare and employee-sponsored plans would pay 20% of the cost of the plan. Each plan had cost sharing mechanisms and catastrophic out-of-pocket limits. The prescription drug benefits under the Administration plan are summarized in Table 2.1.

Table 2.1: Prescription Drug Benefits Under the Health Security Act

	Low Cost Sharing	High Cost Sharing	Combination	Medicare
Deductible	None	\$250	None in network \$250 out of network	\$250
Copayment/ coinsurance	\$5/Rx in network or 20% out of network	20% after deductible	\$5/Rx in network 20% after deductible out of network	20% after deductible
Annual limit- out of pocket	\$1,500 (all expenditures)	\$1,500 (all expenditures)	\$1,500 (all expenditures)	\$1,000 (drugs only)

Source : Grabowski, 1994

The addition of the outpatient drug benefit to Medicare would have cost an estimated \$66 billion between 1995-2000 (O'Sullivan, 1994). The reimbursement and rebate rules would be similar to those already used for Medicaid. Pharmacists would be reimbursed 93% of average wholesale price (AWP) plus a \$5 dispensing fee. Reimbursement would also be limited to median price of all possible substitutes. The manufacturer rebate requirement would be the larger of either 17% of average manufacturer retail price (AMRP) or the difference between AMRP and the sale price. The Secretary of HHS could negotiate supplementary rebates on new drugs with "excessive" prices or drugs for which prices were lower in other countries. The rebate could also have increased if drug prices rose faster than overall inflation. An important difference between the proposed Medicare rebate and the current Medicaid rebate is that generic drugs would be excluded from the rebate requirement under the proposed plan.

Another cost control approach of the Administration plan was the creation of an Advisory Council on Breakthrough Drugs. The Council could not set prices, but would evaluate the "reasonableness" of prices on new drugs and report them publicly. It was envisioned that the Council could help raise public pressure on manufacturers who were judged to be charging excessive prices.

According to CBO estimates, out-of-pocket expenditures on prescription drugs under the Administration plan would have dropped from about 50 percent to 20 percent of total costs. Total expenditures would have increased by between 5 and 7 percent, and manufacturer profitability would increase by about 3 percent. Total R&D investment would not be greatly affected, but the focus of R&D efforts would switch from older age group illnesses to younger age group ailments (CBO, 1994).

Modifications of the Administration plan were proposed in both the House and the Senate. For example, the Gephardt bill (H.R. 3600) was based primarily on the House Ways and Means Committee bill and would have expanded the Medicare program to cover uninsured individuals and employees of small firms under Medicare Part C. The

Table 2.2: Major Health Care Proposals in the 103rd Congress

	Gephardt bill (H.R. 3600)	Mitchell bill (S. 2357)	Dole bill (S. 2374)	Mainstream Coalition proposal
Outpatient Drug Benefit	Prescription drug coverage included in standard benefit plan.	Categories of required covered services were specified in statute and included prescription drug coverage. Federal board would have defined scope and duration of coverage.	Would establish minimum categories of services that must be covered for the individual and small group markets (50 people or less); prescription drug coverage included.	Specified categories of required covered services, including prescription drug coverage. Federal commission would have defined scope and duration of coverage. A high cost sharing plan designed by the commission may not have included drug coverage.
Cost Sharing	<p>Fee for Service: \$500 drug deductible 20% drug co-insurance \$1,000 drug out-of-pocket limit</p> <p>Managed Care: \$10/prescription</p>	Cost sharing for fee for service, HMO, preferred provider, and point of service plans would have been set by the federal board.	HHS would have set cost sharing for fee for service, HMO, preferred provider, and point of service plans providing standard individual and small group benefit plan.	Cost sharing for plans with various delivery systems would have been set by the commission.
Medicare Outpatient Drug Coverage	Drugs would have been covered effective 1/1/98 as a separate benefit with \$500 deductible, 20% co-insurance, and a \$1,000 out-of-pocket limit (in 1994 dollars)	Drugs would have been covered effective 1/1/99 as a separate benefit with an unspecified deductible (CBO estimated at \$700), 20% co-insurance and a \$1,275 out-of-pocket limit.	not applicable	not addressed
Medicare Access Restrictions	HHS Secretary would have authority to require prior authorization for all drugs and authority to oversee off-label uses.	Prior authorization would have been required for some drugs. HHS Secretary could have required advance approval for drugs for which a cost-effective, therapeutic equivalent is available. HHS Secretary also would have had authority over off-label uses.	not applicable	not applicable
Medicare Rebate	15% for brand drugs and 10% for OTC insulin. Additional rebates for brand drug price increases exceeding CPI. Unitary pricing provisions were included.	15% for brand drugs and 6% for generic drugs. Additional rebates for brand drug with prices increases exceeding CPI.	not applicable	not applicable
Expanding Access	Individuals would have been required to enroll in a private health plan or Medicare Part C by 1999. Other stipulations included tax credits for small, low-wage employers; phased in subsidies for people below 240% of poverty; and an employer mandate of 80% of premiums in 1997 for large firms (>100) and 1999 for small firms (<=100).	<p>An employer mandate for firms (>25 employees) would have taken effect within states that had not achieved 95% coverage by 2000, if national universal coverage legislation was not enacted by that time.</p> <p>Five-year decreasing subsidies would have been available to firms expanding coverage. Subsidies provided to people below 200% of poverty (240% for children and pregnant women.)</p>	Subsidies provided to individuals with incomes below 150% of poverty that do not have employer provided coverage. Total premium subsidies constrained by an annual subsidy spending limit.	If 95% coverage was not reached by 2002, commission would make unbinding recommendations to Congress to meet target. Subsidies would have been phased in for people below 200% of poverty (240% for children and pregnant women.)

Source: Pharmaceutical Research and Manufacturers of America, 1994

Mitchell bill (S. 2357) followed the Senate Finance Committee bill closely, but included a Medicare outpatient drug benefit and an employer mandate.

Two other major health reform proposals introduced in the 103rd Congress were Senator Dole's reform proposal (S. 2374) and the bipartisan Chafee-Breaux (Senate Mainstream Coalition) plan. A summary of the four major plans' prescription drug provisions is given in Table 2.2.

In addition to these four plans, a variety of alternative plans were discussed and proposed. Representative Rowland proposed a bipartisan amendment to the House Leadership bill which would have automatically triggered reductions in low income subsidies if the health care plan increased the federal deficit. In addition, the Rowland plan would have prohibited punitive or exemplary damages against manufacturers if products complied with FDA approval requirements. The McDermott bill (H.R. 1200) would have created a single-payer system with a national drug formulary and national practice standards, and had no cost sharing.

Conclusion

While comprehensive federal health reform was not passed in the last Congress, the issue of the federal role in prescription drug payment is still an important one. Given that the current debate has been on how to reduce costs of the Medicaid and Medicare systems, federal policy makers may need a framework for understanding the proposals of proposals that allow greater savings in the Medicaid drug benefit. In addition, policy makers may need to understand how the greater use of managed care in state Medicaid programs--as well proposed managed care options in the Medicare program--may offer new ways of providing a prescription drug benefit that also have implications on the market.

Furthermore, a future Congress may return to the issue of comprehensive health reform and, in particular, issues surrounding the provision and pricing of prescription drugs. Alternatively, a return to the trend of rapidly growing prescription drug prices may again bring calls from some government officials for drug pricing regulations. A framework for understanding the implications of alternative federal drug payment policies would be extremely useful in either of these circumstances.

The next chapter presents a review of the literature on the impacts of various drug payment policies that provides a starting point for modeling those impacts.

CHAPTER 3

LITERATURE ON THE EFFECTS OF PHARMACEUTICAL SPENDING CONTROL POLICIES

Introduction

A wide variety of approaches have been used to restrain prescription drug costs to both public and private third-party payers in both the United States and other industrialized countries. While a number of studies have examined the impact of these policies, the literature tends to be incomplete and inconclusive concerning the overall effects of the various approaches. There have been no comprehensive studies of the many impacts of policies; rather, the studies have generally focused only on particular aspects of policies. Some studies have examined the effects of policies from the perspective of whether they save costs or reduce access, while others have evaluated the impact on R&D and drug innovation, still others have focused on competitive aspects of a drug payment policy. Furthermore, as is outlined in the discussion below, the results of some studies should be viewed with caution because they did not control for factors that may influence behavior other than the policy being reviewed. In addition, of the available studies of policies of drug spending control approaches in the United States, many more focus on the Medicaid program than on private approaches.

Efforts to restrain prescription drug costs have been applied by both private and public sector payers. Policies that have been implemented, both in the United States and internationally, are listed in Table 3.1. These policies are grouped into categories of the level at which cost containment strategy is focused. The discussion of these cost containment mechanisms below follows the organization presented in the table.

Table 3.1: Menu of Prescription Drug Spending Control Policies

Patient Based Approaches	Cost Sharing Prescription or total spending limits
Provider and Pharmacy Based Approaches	Formularies Physician drug budgets Physician benchmarking Drug utilization review Limits on pharmacy dispensing fees
Manufacturer Based Approaches	Manufacturer rebates Price review boards for patented drugs Price and profit controls
Market Based Approaches	Promoting direct product competition (generic and non generic) Use of managed care approaches for pharmacy benefits Cost effectiveness analyses

Patient Based Approaches

One set of prescription drug cost control policies is aimed at increasing price sensitivity on the part of drug consumers. While insurance coverage provides benefits to society--by reducing uncertainty of consumer expenses and reducing financial barriers to necessary prescription drugs--it also creates inefficiencies in prescription drug consumption. Insurance coverage reduces the effective price of drugs, leaving consumers with fewer incentives to choose an efficient level of drug utilization.

When consumers have insurance, they are less sensitive to differences in price between brand name drugs and their generic substitutes, between therapeutically similar brand name drugs, and between drug and non-drug therapies. In the extreme, when consumers have 100 percent drug coverage, they have no financial incentive to choose less expensive generic products, or to analyze the relative costs of other types of therapeutic substitutes. Price insensitivity results in higher consumption levels and increased costs for third-party payers. It also creates a welfare loss for society as the increased utilization takes resources from more efficient uses.

For public programs, such as Medicaid and European social insurance systems, the increased societal cost of higher utilization may exceed the amount that society is willing to pay for increasing access to pharmaceuticals. Private insurers, too, have been facing pressures to reduce the costs of pharmaceutical benefits. In such cases, private or public third-party payers may try to achieve more efficient drug utilization by taking measures to increase consumer sensitivity to drug prices.

The impact of these approaches will depend on the extent to which drug prices affect consumption levels. Only a few studies in the economics literature that try to estimate the elasticity of demand for prescription drugs with different levels of drug coverage. Studies of changes in copayments in the United Kingdom estimated prescription drug price elasticities ranging from -0.06 to -0.64, with the preponderance of estimates in the -0.10 to -0.20 range. In the United States, a study of elderly Medicare recipients in Pennsylvania suggested that coverage by the state's PACE program (which subsidized the cost of prescription drugs to low-income elderly) had an own price prescription drug elasticity of -0.34 (Stuart, et al., 1994).¹ Unfortunately, the RAND health insurance experiment--perhaps the most famous and comprehensive health demand study--did not make estimates of demand elasticity for prescription drugs available because health insurance packages offered in that experiment did not vary according to prescription drug benefits.

Two types of patient based approaches for restraining drug benefit costs have been studied in the literature. The first type examines policies that use cost sharing mechanisms

¹ The program was observed to increase demand for people who did not consume prescription drugs in the absence of insurance coverage. It had no statistical impact on the number of medicines used by persons filling one or more prescriptions per month.

to reduce patient demand for drugs. The second type looks at limits on the number of prescriptions for which an insurer will pay.

Cost Sharing

Drug benefits that include cost sharing components are designed to increase consumer sensitivity to drug prices by increasing the share of drug costs paid by consumers. Application of cost sharing can be expected to affect the cost of a prescription drug benefit in two ways. First, drug benefit costs would be reduced to the extent that payments have been shifted from the benefit plan to the consumer. Second, the quantity of drugs purchased would likely decrease as a result of the higher effective price paid by consumers.

Some advocates of increases in cost sharing suggest that low levels of cost sharing will reduce overconsumption of prescription drugs and reduce the use of drugs of questionable medical efficacy. However, a sufficiently high level of cost sharing (either in absolute terms or as a percentage of income) can potentially reduce both necessary and unnecessary consumption. To the extent that this reduced consumption leads to adverse health consequences, there may be a net increase in both prescriptions required and in the use of other health services. Therefore, the high cost sharing may lead to additional increases in drug benefit costs or higher spending on related health services.

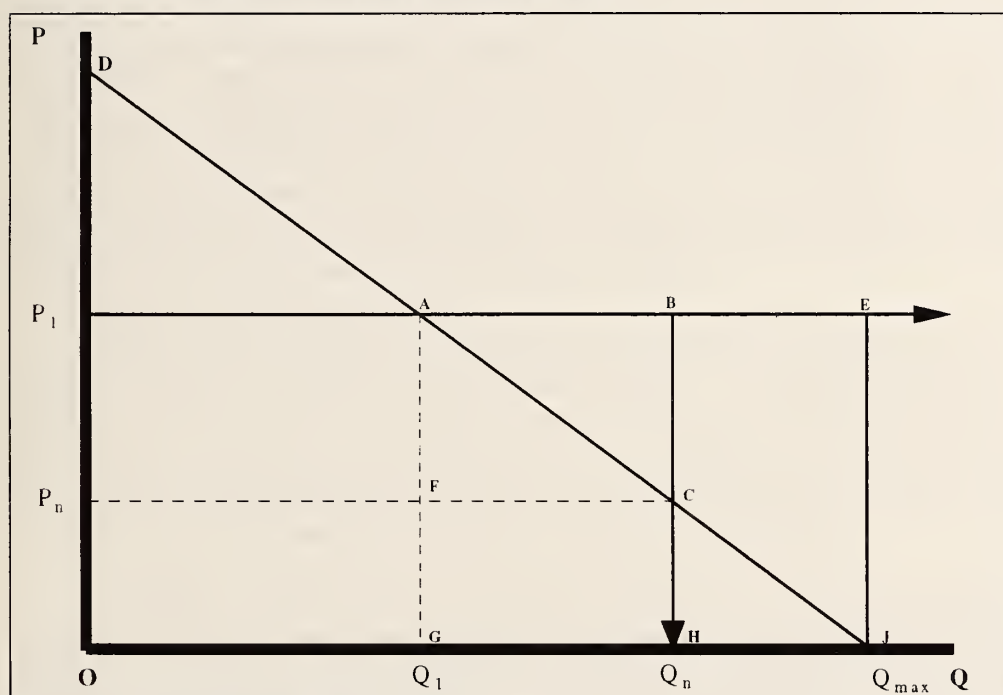
The specific cost sharing instrument can take any of three different forms:

- *deductibles*--financial outlays that must be paid before the consumer can receive benefits. For example, a program with a \$100 deductible would require consumers to spend \$100 before becoming eligible for benefits.
- *co-insurance*--a requirement that the consumer pay a fixed percentage of expenditures. A co-insurance policy could require the consumer to pay 20 percent of costs.
- *copayments*--payments by the individual of a fixed dollar amount per unit of service consumed. For example, consumers may face a copayment of \$2, \$5, or \$10 per prescription.

McMillan and Jankel (1993) describe the theoretical arguments behind increasing prescription drug cost sharing to consumers. Advocates of increases in cost sharing suggest that low levels of cost sharing will reduce unnecessary or inefficient consumption of prescription drugs. As illustrated in Figure 3.1, consumers targeted for a subsidized program are assumed to have a medical need for quantity Q_n of drugs, but at market prices P_1 could only afford to purchase quantity $Q_1 < Q_n$ (as shown by the demand curve DJ). If society decided to provide a 100 percent subsidy in drug consumption--in effect, trading the cost of a price subsidy in order to increase equity in pharmaceutical access--then prices to the consumer would fall to zero, and consumption would reach Q_{max} . The new

consumption affects consumer welfare in two ways: area AJG represents a gain in consumer surplus from new consumption, and area OP_1AG represents the amount previously paid by consumers which is now consumer surplus. Government expenditures become area OP_1EJ , but exceed consumer surplus by area AEJ . McMillan and Jankel interpret area AEJ as welfare loss. However, a more precise interpretation of area AED is the excess cost that government is willing to pay to provide the social benefit of universal access to Q_{max} . In addition, the government is paying $BEJH$ for a level of consumption ($Q_{max} - Q_n$) beyond that needed for good health, representing a further inefficient use of government resources. Of this amount, area $CBEJ$ represents a payment that exceeds consumer willingness-to-pay for these benefits.

Figure 3.1: Welfare Cost and Medical Need



Source: McMillan and Jankel, 1993

Cost sharing, in theory, will raise the price of the consumer to bring consumption back to a level closer to Q_n . If successfully implemented, it would reduce excess government costs to area ABC , which might closer represent the tradeoff that society is willing to pay for increased access to drugs (assuming that society wants persons with low income to be able to purchase all medically necessary drugs). Assuming that drugs are ranked in order of marginal utility, the foregone consumer utilization represents products that are of relatively low use to consumers.

McMillan and Jankel suggested that cost sharing, in practice, may not have the desired impact on reducing consumption without reducing necessary consumption, particularly among low income populations. They noted that deductibles, which require the consumer to meet a fixed limit before receiving any benefits, may be financially

prohibitive to some low income beneficiaries--regardless of whether the drug is useful or not. This not only reduces access to necessary drugs (that is, making it less likely that consumers will be able to purchase Q_n), but may lead to an increase in the utilization of other medical services for which reimbursement is provided. Furthermore, once the deductible is met, then reimbursement is provided for additional products regardless of utility. This could result in continued consumption of drugs which provide low marginal utility. McMillan and Jankel also questioned whether consumers have sufficient technical knowledge for ranking drugs in order of marginal utility. They cite studies of the imposition of cost sharing in which reductions in drug use cuts across categories, regardless of utility level.

In practice, cost sharing has been used extensively in the United States to limit drug benefit costs in both the public and private sector programs. Even in the Medicaid program, cost sharing became a widespread cost-containment strategy during the 1970s and 1980s. Seventeen states had imposed cost sharing on prescription drugs in Medicaid programs by 1980; these increased to 29 states by 1993 (National Pharmaceutical Council, 1994). Countries with social insurance systems have been increasing the use of cost sharing in recent years as a way to control the growth of prescription drug benefit costs. France, Germany, the United Kingdom, and Sweden have all increased consumer cost sharing for pharmaceuticals since 1989 (GAO, 1994a).

Most published analyses on the effects of government imposed cost controls have focused on those imposed in state Medicaid systems. As noted in extensive reviews by Reeder, et al. (1993) and Soumerai, et al. (1993), many of these studies do not offer generalizable lessons of cost sharing impacts. Soumerai, et al., in particular, found that these studies are often flawed in that they do not have adequate comparison groups or do not fully control for unrelated factors that might affect the results.

Of those studies that do adequately control for intervening factors, the most significant finding confirms the decreased utilization of prescription drugs that typically results in imposition of cost sharing. For example, prescription drug consumption with different levels of co-insurance was one aspect of health services observed in the RAND Health Insurance Experiment, which ran from 1974 to 1981. While the insurance plans in this experiment did not vary in their level of drug copayment, copayments did vary for physician services, which is highly correlated with pharmaceutical utilization (Feldstein, 1994). In the RAND experiment, prescription drug spending was highest with 100 percent coverage, but was 20 percent lower for plans with a 25 percent co-insurance rate, and 57 percent lower for plans with a 95 percent co-insurance rate. (Liebowitz, et al., 1985; CBO, 1993).

This pattern of decreased drug consumption is observed even when copayments are applied at low levels. Nelson, et al. (1984), Reeder and Nelson (1985), and Soumerai, et al. (1987) found that Medicaid enrollees and other low income populations were sensitive to copayments as low as \$0.50 to \$1.00 per prescription. Harris, et al. (1990), studying the introduction of copayments in a staff model HMO, observed a 10.7

percent drop in the number of prescriptions relative to a comparison group when a \$1.50 copayment was introduced, and another 10.6 percent drop when the copayment was increased to \$3.00. Levy (1992) reported decreased utilization with the implementation of copayments in both the Medicaid and managed care sectors. D. Smith (1993) observed a 5 percent drop in utilization for HMO members when a copayment was increased from \$3 to \$5 per prescription.

In contrast to the previously mentioned studies, Stuart, et. al. (1994) provide insight on the impact of *decreasing* the cost sharing amount. This study measured the impact of pharmaceutical insurance coverage for elderly Medicare recipients in Pennsylvania. The study provided three methodological advances over previous analyses: first, it analyzed the effect of insurance coverage over a wide range of copayment levels; second, it separated the own price effect of prescription drug coverage from the impact of subsidies on complements of prescription drug use (such as physician services); and third, it separated the impact of moral hazard on elderly choice of prescription drug benefit. The analysis was performed for a sample of over 4,000 Pennsylvanians who had different forms of insurance coverage, including Medigap policies, private employer coverage, and enrollment in PACE (a state program that subsidizes the cost of prescription drugs for low income elderly in Pennsylvania). Stuart, et al. found that PACE, in particular, had a significant impact on prescription drug use. PACE beneficiaries filled 0.29 more prescriptions per two-week period than did those elderly who had no outpatient prescription drug coverage. They also found that the major impact of prescription drug coverage was to induce demand for those who would not use any drugs in the absence of coverage. At mean values, PACE enrollment increased the probability of drug use by 11 percent, while coverage for physician care services raised the probability by 5 percent.

As noted by Reeder, et al. (1993), there are several gaps in the literature regarding the impacts of cost sharing. Little is known about the appropriateness of cost sharing for low income groups--in particular, at what level utilization drops for essential drugs. That negative impacts can occur has been documented by Reeder and Nelson (1985) and Soumerai, et al. (1987), each of whom observed reductions in the use of both essential and non-essential drugs when a Medicaid copayment was introduced. Reeder, et al. also noted the uncertainty regarding the relationship between increases in cost sharing on pharmaceuticals and the utilization of other drugs or other health services. There is some evidence that the decrease in drug utilization associated with cost sharing may increase the use of other health services (Reeder, et al., 1993; Soumerai, et al., 1993). As a result, the long term consequences of cost sharing are not well understood.

Caps on Prescriptions or Total Drug Spending

The application of prescription caps is an attempt to impose budgets on the dispensing of prescription drugs. Two different types of caps have been evaluated in the literature. One cap is the application of limits on the number of prescriptions that a program beneficiary may receive in a single time period. Such a cap, applied to Medicaid beneficiaries in New Hampshire in 1981, was both a cost cutting move and an attempt to increase the cost consciousness of program beneficiaries.

The effect of New Hampshire's prescription drug cap was examined by Soumerai, et al. (1987; 1991). The cap imposed a three drug limit on Medicaid beneficiaries. The data followed a cohort of 11,000 patients, including 860 at-risk patients who were on multiple drugs and were overwhelmingly disabled or elderly. The cap caused a sudden, sustained drop in prescriptions per patient, from 1.1 to 0.7 per month. While the short-term result was a savings in Medicaid costs (an estimated \$4-8 billion during the one year the policy was in effect), Soumerai, et al. reported that the cap had serious implications for the health of at-risk patients and increased the likelihood of nursing home admissions.

The cap was in place for only one year, after which it was replaced with a \$1.00 copayment. This policy shift led to an increase in drug utilization, although at a level still below the pre-cap levels. It also was associated with a reduced risk of nursing home admissions. Medicaid program savings under the co-payment policy were comparable to those achieved under the cap.

Provider and Pharmacy Based Approaches

The next level of cost containment mechanisms and policies focuses on providers and pharmacists. These policies are intended to control prescription drug expenses by increasing the cost awareness of physicians and pharmacists. A variety of strategies are used, including cost effectiveness and prescribing education, financial incentives, and prescribing limitations. These types of policies have been adopted by private insurers, the Medicaid program, and internationally, as well.

Drug Utilization Review

Drug utilization review (DUR) has been used for many years by managed care organizations and state Medicaid programs in an attempt to contain unnecessary costs caused by both therapeutic and economic misuse of drugs. DUR has been defined as an authorized, structured and continuing program that reviews, analyzes and interprets patterns of drug usage in a given health care delivery system against predetermined standards and includes effort to correct patterns of drug use that are not consistent with these standards (Kozma, et al., 1993). There are two levels of DUR:

- *Prospective DUR (pro-DUR)* includes all review which is done prior to the purchasing transaction. This can include pharmacist counseling of patients and physicians regarding cost effective and clinically appropriate prescribing; computerized on-line review; and may even incorporate prior authorization mechanisms. Computer-based review may include detailed safety information, as well as cost effectiveness review. Decisions on reimbursement or on filling prescriptions can be made before sale based on prospective DUR.
- *Retrospective DUR (retro-DUR)* involves review of pharmacy claims data to uncover problem patterns in physician prescribing, pharmacist dispensing, or patient drug use.

Retrospective intervention typically takes the form of corrective counseling and provider education, but can lead to financial penalties or more serious actions.

Since the implementation of OBRA '90, all state Medicaid programs have been required to implement DUR programs, including pro-DUR, retro-DUR, and educational outreach. HHS's Office of the Inspector General (1995) reviewed lessons learned by states in implementing and operating the mandated DUR programs. Their report concluded that successful DUR programs needed to develop credible drug use criteria and to be selective and specific when applying these criteria. In addition, the report stressed the need for strong communication between DUR programs, providers and pharmacists, including: tailored letters to problem providers, monitoring pharmacist compliance and proactive pharmacist and physician education through mail and electronic means. A final suggestion was the need to establish on-going research efforts to help guide the program.

The literature is divided on the effectiveness of DUR programs, both public and private. According to Kreling and Mott (1993), most studies of DUR reveal little about the cost effectiveness of DUR in outpatient settings. Kreling and Mott performed a comprehensive review of over 48 DUR studies and reports and concluded that existing literature concentrates on physician prescribing patterns and does not adequately address economic perspectives. They also noted that, overall, the results reported in the literature simply reflected the goals and interests of those conducting the research.

In a recent study which did address the economic perspectives of DUR, Smalley, et al. (1995) evaluated the impact of prior authorization of nonsteroidal anti-inflammatory drugs (NSAIDs) in the Tennessee Medicaid program. The study focused the effect of a prior-authorization aspect of on-line DUR developed as a result of OBRA '90. Smalley, et al. analyzed the policy effect on prescriptions for NSAIDs, prescriptions for other analgesic or anti-inflammatory drugs, and psychotropic drugs. They also looked at use of outpatient services and inpatient admissions. Two study groups were analyzed: all Medicaid enrollees and only "regular NSAID users." Time series analysis of data during the year before policy implementation (October, 1989) and the two years following the implementation showed a decrease of 53% in NSAID expenditures and 19% in days of NSAID use for the entire Medicaid program. Decreases of 64% in NSAID expenditures and 28% in the number of days were exhibited by "regular users." Smalley, et al. found no evidence that the use of other services increased after the policy change. They concluded that preferential use of less expensive NSAIDs could result annually in \$1 billion national savings.

Despite its cost-saving potential, critics feel that the problems with the use of computer-based DUR outweigh its advantages. Soumerai and Lipton (1995) argued against federally mandated use of computer-based drug-utilization review, reflecting their concern regarding evidence on the efficacy and safety of such programs. They cite recent analyses suggesting that the review criteria obtained from five authoritative drug compendiums differ substantially in content and scope. They also argued that agreement between computer-derived alerts and expert opinions has been as low as 10 percent.

Furthermore, they criticized past studies for their statistical biases and for not examining the effect of DUR on patient outcomes.

In contrast to Soumerai, Kralewski, et al. (1994), in studying DUR in the private sector, found that most DUR programs were productive and efficient. They reported that most firms estimated that every dollar invested in DUR results in at least two to three dollars in savings resulted from controlling overutilization and complying with formulary guidelines. They also found that firms reported drug therapy problems in about two to three percent of enrollees receiving prescriptions.

Physician Benchmarking

Physician benchmarking is closely related to DUR. Physician benchmarking, used by some managed care organization in the U.S. as well as in the U.K.'s national health system, involves setting targets or benchmarks for physician prescribing. These targets may be based on the patient mix of the physician, prescribing trends among similar physicians, and the level of utilization of generic and formulary drugs desired by the payer. The targets are meant to be only guidelines for physicians, but patterns of overprescribing can be penalized in some benchmarking programs.

There has been little published study of the impact of physician benchmarking. One of the few examples of policies reviewed is the United Kingdom's physician benchmarking strategy. In the United Kingdom, the government's National Health Service (NHS) furnishes physicians with periodic reports on the volume and cost of drugs prescribed compared to physician averages in their area. In addition, the Indicative Prescribing Scheme (IPS) gives physician financial prescribing benchmarks based on historical expenditures, demographics of their patient base, drug price inflation and other factors. These targets are not binding caps, but physicians who consistently surpass their benchmarks can be targeted for advice and monitoring, and as a last resort, physicians can be financially penalized (GAO, 1994a). NHS officials believe that this strategy has reduced the cost of its prescription drug benefit, but no rigorous study of its effects is available.

Controls on Dispensing Costs

An additional method for controlling costs through pharmacists is setting limits on dispensing fees. Controls on pharmacy dispensing costs are common in Europe (GAO, 1994a) and, in this country, they have been used in state Medicaid programs and by many private payers. Dispensing fees have been used in conjunction with the Maximum Allowable Cost/Estimated Acquisition Cost program (see p. 3-18), where pharmacists are reimbursed the ingredient cost plus a set dispensing fee minus any copayment. The fees are intended to prevent pharmacists from making excessive profits from sales to Medicaid patients. Dispensing fees among state Medicaid programs vary widely, ranging from \$2.00 to \$11.46 per prescription in 1993 (National Pharmaceutical Council, 1994). The

Connecticut and New Hampshire programs offer an additional financial incentive above the standard dispensing fee to pharmacists who dispense lower cost substitute products.

Adams, et al. (1994) developed estimates of “appropriate” state dispensing fees and then evaluated the adequacy of current payments. Appropriate dispensing fees were determined using pharmacy level data for 22 states, calculating an average dispensing fee using weights for the proportion of chain and community pharmacies, and adjusting for inflation. They estimated a national dispensing cost of \$6.08 for 1991. This result was indexed to state-level dispensing costs using a state-index for measuring variation in costs between urban and rural areas. Adams, et al. noted that nearly every state underpaid pharmacists for dispensing services, but noted that in most states this effect was balanced by overreimbursing for ingredients. In sum, they concluded that payments are more than adequate to induce pharmacy participation in Medicaid programs.

European countries have also placed limits on pharmacist reimbursement. In France, pharmacists are paid a markup on manufacturer price, in which the percentage payment decreases in proportion to the drug’s price. In Germany, pharmacist markups also decrease with increases in the price of the product, ranging from 30 to 68 percent of wholesale price. In Sweden, the pharmacist margin is set at a flat 41 percent of wholesale price. In the United Kingdom, the pharmacist margin is combined with the wholesale margin and is limited to 12.5 percent of the retail price. In addition, pharmacists receive a per prescription dispensing fee, which decreases after the first 1,500 prescriptions (GAO, 1994a). GAO’s four country study (1994a) credits overall drug regulation with lowering drug prices in these countries, but not necessarily in restraining drug spending. The degree to which these policies contribute to lower prices or drug expenditures in these countries has not been analyzed, however.

Formularies

Formularies are drug lists that are used to deny reimbursement for specific drug entities or drug classes, or to encourage the use of certain drugs that are deemed more cost or medically effective than other drugs. (Kozma, et al., 1993; NPC, 1994). As a cost control measure, they are designed to make prescribers aware of the relative costs of alternative drugs, or to limit expenditures on drugs that are not viewed as cost-effective in most cases.

Formularies vary greatly in their degree of restrictiveness. At one extreme are open formularies, which provide prescribing guidelines but do not restrict reimbursement for particular drugs. At the other extreme are closed formularies which deny reimbursement for certain products. In between are formularies that have differential copayments for more expensive products. The degree of restrictiveness generally varies from payer to payer in the number of products denied and in the denial or acceptance of entire therapeutic categories. For some restrictive formularies, payment on restricted drugs may only be subject to prior authorization requirements. As a result, a “restrictive”

formulary may, in reality, not be restrictive if the vast majority of prior authorization requests are granted. (Schweitzer and Shiota, 1992)

Formularies have been widely used in the private sector--particularly by hospitals and HMOs--and by the Medicaid program. An estimated 90 percent of private hospitals have formularies in place (NPC, 1994). In the managed care area, over 90 percent of surveyed HMOs used drug formularies in 1993 (Ciba-Geigy, 1994), an increase from 39 percent in 1989 (Managed Care Digest, 1993). Staff model HMOs are more likely to use restrictive formularies, while IPAs are more likely to use an open model, as do many HMOs and pharmacy benefits managers (NPC, 1994).

Formularies have also been widely used in public programs as well, both in the United States and abroad. In 1990, 20 state Medicaid programs had drug formularies in place (Moore and Newman, 1993). Formulary use was relaxed as a result of passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), in which states agreed to lift formulary restrictions for those manufacturers agreeing to pay a rebate, but OBRA '93 gave states the authority to again establish formularies even when a rebate was in place (NPC, 1994).² Formularies or similar types of drug lists are used by social insurers in many countries, including Canada, the United Kingdom, and France (GAO, 1992; GAO, 1994a).

Most of the published studies examining the effects of formularies have focused on Medicaid program formularies. With a few notable exceptions, these studies are of limited use in explaining the impact of formularies on state Medicaid spending (Schweitzer and Shiota, 1992). For example, those studies that examine trends in individual state Medicaid programs may be more reflective of idiosyncrasies in each state's formulary restrictions than of a generalizable pattern. Many of the studies do not assess the impact of policy or environmental changes that accompanied the implementation of the formulary restrictions, thereby making it difficult to evaluate causality of spending trends. Furthermore, these studies only monitor the short-term effects of formulary restrictions, and do not consider the long-term consequences of new physician prescribing or treatment patterns.³

The methodological issues described above make it difficult to design studies that allow for an adequate evaluation of the impact of formularies. For example, one conclusion drawn from studies of Medicaid formularies is that they shift utilization to other prescription drugs--sometimes to more expensive drugs or to drugs of questionable value (Hammel, 1972; Kreling, et al., 1989; Smith and MacLayton, 1977). Two of these studies, however--Kreling, et al. and Smith and MacLayton--lack the controls necessary to

² Under the provisions of OBRA '93, state Medicaid programs may use formularies to restrict coverage for some drugs, provided that an excluded drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes" over other products. Excluded drugs must be available through prior authorization.

³ An additional concern raised by some observers is the possible bias arising from pharmaceutical industry financing of some of the studies.

isolate the impacts of the formularies (Soumerai, et al., 1993). As for the Hammel study, some of the results reported are somewhat counterintuitive. Specifically, Hammel observes increased use of services that are not associated with the drugs being withdrawn from the formulary. Soumerai, et al. suggest that Hammel's model may be capturing other factors that are not adequately measured in the analysis.

Other studies differ from one another in interpreting the impact of formularies on health care cost savings. Harr and Logerfo (1977) found that a Medicaid restriction on benzodiazepene led to a 70 percent decrease in nonformulary prescriptions and no corresponding increase in the prescribing of similar formulary drugs. By contrast, Taubman (1972; cited in Kozma, et al., 1993) finds no difference in per capita expenditures based on the degree of formulary restrictiveness. Soumerai, et al. (1990), in examining the withdrawal of 12 drugs from the New Jersey Medicaid formulary, found no measurable reduction in overall drug utilization or expenditures over a 42 month period. He concluded that the reduced use of these drugs, which had been determined by the State Medicaid program to be of questionable effectiveness, was offset by equal or greater increases in the use of substitute drugs.

A more recent study, which addresses many of the criticisms cited of other studies, suggests that Medicaid formularies have indeed lowered per capita Medicaid drug spending. Moore and Newman (1993) used pooled cross-sectional state data on Medicaid expenditures from 1985 and 1989 to examine the impact of state drug formularies. They assert that these data allow them to capture the long-term impact of formularies because most of the formularies had been in place for a decade or more. Their analysis isolates the impact of formularies from state economic variables, characteristics of each state's Medicaid program, and state Medicaid cost containment mechanisms. Their findings suggest that restrictive formularies had a significant negative impact on per capita drug expenditures (with an average decrease of 14.8% of per capita drug expenditures).

The literature is similarly ambiguous on the extent to which formulary restrictions lead to increases in non-pharmaceutical spending. The service substitution hypothesis suggests that the reimbursement restrictions on drugs lead patients and providers to substitute other services that are eligible for Medicaid reimbursement. Moore and Newman (1993) found evidence to support this hypothesis. Their analysis suggested that drug formularies had no significant effect on total Medicaid expenditures; in effect, pharmacy cost savings were offset by increases in other services. Similarly, Bloom and Jacobs (1985) found that restrictions in prescribing the anti-ulcer drug cimetidine were associated with a 24 percent increase in hospital costs. However, while Moore and Newman were able to compare formulary and non-formulary programs, Bloom and Jacobs' study lacked a comparison group. As noted by Soumerai, et al. (1993), the effects they measure may have been associated with other cost containment efforts being carried out simultaneously. Soumerai, et al. also suggest that biases in the Bloom and Jacobs study may have resulted from having a relatively sicker group of patients during part of the study. Other studies obtain findings that contrast with the service substitution hypothesis. In particular, Schweitzer, et al. (1985) found that restrictive formularies in

seven states they examined were associated with a decrease in total Medicaid expenditures, even though there was no apparent reduction in Medicaid drug expenditures. They contend that this finding suggest that the existence of a formulary was as a proxy for other Medicaid cost containment programs).

Some analyses of formularies' impacts have suggested that formularies restrict Medicaid beneficiaries' access to new drugs. These restrictions are associated with a time lag between the time of product approval and placement on the state's Medicaid drug formulary. Schweitzer, et al. (1985) studied trends in drugs being put on Medicaid formularies in seven states from 1970-1980. They found that the average approval lag varied from one year to over five years, although the lag decreased over the period of his study. Approval of new drugs in the seven states ranged from 19 percent to 73 percent. Grabowski (1988) found that the typical new drug product for the period examined was available to Medicaid beneficiaries for only two of the first five years of product life. These restrictions applied to "me-too" drugs as well as to therapeutic improvements. The restrictions also were on drugs that were widely used in the non-therapeutic market. Anti-infectious drugs, psychotherapeutics, and anti-fertility drugs were the least available.

In a larger study, Grabowski et. al. (1991 unpublished; cited by Schweitzer and Shiota, 1992) found that the typical new drug compound had a 20 month delay in getting on formularies between 1979-1985, and was available less than 40 percent of the first four years of its product life. Anti-infectives and psychotropic drugs were among the most restrictive. New drugs of commercial and therapeutic importance in several categories were not on some formularies. California had the most restrictive formulary and the longest lag in the states studied; New York the least restrictive and with an average delay of only 8 months. Schweitzer and Shiota note, however, that these results may overstate the impact of California's restrictions, since the state also had in place a prior authorization program that enabled access to nonformulary products.

Moore and Newman (1993) suggest that drug formularies have reduced the quality of benefits provided to Medicaid beneficiaries. They test two separate hypotheses: first, that formularies are designed to reduce the average price of drugs while leaving quality unchanged; and second, that they are designed to eliminate classes of drugs while leaving average prices unchanged. Their statistical tests suggest that both of these hypotheses can be rejected. That is, formularies result in a decrease in price and in the quantity of prescriptions dispensed. Moore and Newman suggest that restricting the choice of prescriptions results in a reduction in the quality of prescriptions.

Moore and Newman's finding suggests a direct correlation between the reduction in prescriptions and the quality of prescribing. However, the data they analyze are insufficient to make this judgment. Specifically, they offered no assessment of the therapeutic value of drugs which were excluded. On the one hand, the products may indeed have offered significant therapeutic improvement, but drug formulary committees also may seek to reduce both average price and the prescribing of products that offer little or no therapeutic improvement.

Critics of formularies note that they may harm incentives for pharmaceutical R&D because they potentially shift physician choice towards using the least expensive medicine regardless of the benefit (Thomas, 1993). In addition, they feel that formularies may delay the effective market life for drugs, since they lose sales while waiting for the product to get on the formulary (Grabowski, 1991).⁴ Both of these factors have the potential of reducing revenues for new drugs.

Drug Budgets

Perhaps the strictest of the provider-based approaches for restraining prescription drug spending is the use of a global drug budget. This approach was adopted by the German health care financing system in 1993. The spending cap in Germany was a national cap on outpatient prescription drug expenditures. The policy was implemented to reduce the high rate of prescription drug costs in Germany (which accounted for over 20 percent of total health care spending in 1990). It was designed to place the burden of prescription costs on physicians. According to the law passed in 1993, overspending of the budget would result in a decrease in payments made to outpatient physicians. The law was accompanied by increased cost sharing on consumers and a mandated decrease in the price of some prescription drugs. (GAO, 1994c)

The GAO study reported that these policies resulted in a 20 percent reduction in pharmaceutical expenditures between 1992 and 1993. While the German government attributed some of the reduction to the cost sharing and price reductions, it attributed about two-thirds of the savings to a decrease in the number of prescriptions, an increase in the prescribing of therapeutically similar, but less expensive medicines, and a reduction in certain categories of prescriptions that are of questionable value. Despite concerns that the budget would decrease access to important drugs, government statistics show that the bulk of the reductions have been applied to these therapeutically questionable drugs (GAO, 1994c).⁵ Furthermore, there has been a shift from newer medicines toward older, more established medicines as well as a movement toward lower-priced generic substitutes (Münnich and Sullivan, 1994).⁶

⁴ The French health care system provides an example of where such delays occur. Until recently, a new drug could not be reimbursed under the French national health care system until its price (as well as its safety and efficacy) have been approved by the central government (GAO, 1994a). This led to delays in entry of new products.

⁵ Among these drugs are products for treating low blood pressure, vitamins (other than those for pregnant women or people with osteoporosis), mineral preparations, and cholesterol reducing drugs (prescribed before other measures such as changing dietary habits were taken).

⁶ A drug budget's impact on utilization is likely to depend on utilization patterns prior to imposition of the budget. Germany's experience is consistent with a perception of high drug utilization in Germany, especially for drugs of questionable therapeutic value. A different mix of drug utilization could affect access to medically necessary drugs when drug budgets are implemented.

Manufacturer Based Approaches

Manufacturer based approaches are generally designed to prevent or deter drug manufacturers from charging prices and/or earning profits that are considered to be excessive. Many of these policies are designed to give the government access to rebates and discounts that manufacturers provide to their institutional customers. Other policies are directed at overall price containment. However, the effects of these approaches on product innovation and the well-being of the pharmaceutical industry are also of major concern along with controlling costs. Therefore, much of the literature on manufacturer based approaches address these impacts. The manufacturer based approaches discussed in the literature are rebates, price review boards, and price and profit controls.

Rebates

Prior to 1990, Medicaid had been paying near retail prices for prescription drugs, while other purchasers, such as hospitals and HMOs, were able to negotiate significant discounts with drug manufacturers. OBRA '90 contained a provision that required drug manufacturers to give state Medicaid programs rebates for outpatient drugs based on the lowest prices available to any purchaser (GAO, 1993a). The Administration's recent health reform effort also included a rebate on Medicare drug purchases (CBO, 1994).

A Medicare or Medicaid rebate can be viewed as a tax on drug manufacturers that is assessed to help pay the cost of a publicly funded prescription drug benefit. The financial benefits of the rebate accrue to the government, and do not directly reduce the price charged for drugs. Thus, when program beneficiaries have to make copayments (as they would have under proposed Medicare drug benefits), the rebate does not reduce copayment amounts.

In fact, rebates have the potential to raise prices charged to public programs, private consumers, and private third party payers if manufacturers pass on some or all of the rebate costs in the form of higher drug prices. In addition, when the rebate is based on the best price charged by drug manufacturers (as is the Medicaid rebate), it could reduce discounts that have been provided to institutional buyers such as hospitals, managed care organizations, and pharmacy benefits managers.

The U.S. General Accounting Office evaluated the impact of the Medicaid rebate both one and two years after its imposition. The analysis of the effects after the first year involved examination of drug costs for over 800 drugs purchased by HMOs and by group purchasing organizations (GPOs) that typically negotiated drug purchases for hospitals (GAO, 1993a). While GAO was not able to attribute any price changes to the rebate provisions, they found that prices charged to HMOs rose more than twice as much, on average, the year after OBRA '90 than the year before. However, prices on inpatient drugs charged to GPOs increased at a lower rate the year after OBRA '90 than the year before. GAO did not evaluate whether greater price sensitivity on the part of hospitals or other factors contributed to the different price trends.

GAO's second analysis compared HMO and hospital drug prices to changes in the "best price" charged by drug manufacturers. Since the rebate is calculated as a percentage of the difference between manufacturers' best price (the discounted price given to some purchasers) and Average Manufacturer Price (AMP), there was concern that manufacturers would react to the lost Medicaid revenues by raising their best price relative to the AMP, thereby reducing the cost of the rebate. Indeed, GAO found substantial increases in best price that corresponded to a shifting of the rebate cost to private purchasers (GAO, 1994b).

Schondelmeyer, et al. (1995) also evaluated the impact of the OBRA '90 Medicaid drug rebate as it affected program expenditures, utilization and access to outpatient drugs. Schondelmeyer, et al. focused on the changes between 1990 and 1992 and documented total rebates collected and total administrative and start-up costs of the program. After correcting for trends in the number and mix of eligibles, they were able to assess the overall impact of the rebate program on expenditures. They found that the rebate program resulted in a leveling of per capita drug expenditures (in constant dollars) over the first three years of the program. After adjusting for inflation (1993 constant dollars), the average prescription payment less rebates collected in FY1993 (\$18.80) was less than the average Medicaid prescription payment four years earlier (\$19.08). Median administrative costs for 12 states studied grew from \$50,000 to \$90,000 between 1991 and 1993. In contrast, the median annual rebate amount collected for each state was \$20 million. Unfortunately, Schondelmeyer, et al. did not examine the cost shifting effects of the rebate program or its impact on pharmaceutical manufacturers.

KPMG Peat Marwick (1994) evaluated the impact of a potential Medicare drug rebate on the market for generic drugs. This sector was especially interesting because pricing in the generic industry is very competitive (KPMG Peat Marwick, 1994; Caves, et al., 1991). KPMG designed a simulation model for the market for 10 widely dispensed generic drugs to examine the impacts of rebates on product profit margins under a rebate, the likelihood of firms' dropping product lines in reaction to the rebate; and the price reactions of competitors after firms dropped out of the market. Data on prices for this model came from a survey of generic manufacturers. KPMG found that the imposition of a 10 percent Medicare rebate would contribute to an average 3 percent short-run increase in prices for the 10 drugs in their sample, and a long-run price increase of 6 percent. This cost shifting was predicted to result in increased cost sharing by consumers (including Medicare beneficiaries), higher health insurance costs, and relatively low net government revenues from the rebate (since rebate revenues are counterbalanced by increased prices paid by Medicare).

Price Review Boards

Another manufacturer based approach to restraining the cost of a drug benefit is to establish a drug price review board for launch prices and/or price increases. Supporters of price review boards contend that the lack of competitive forces in the pharmaceutical marketplace requires government intervention to prevent drug manufacturers from

charging excessive prices. Their concern is strongest for patented drugs, which by definition lack generic substitutes.

In theory, a price review board does not set or control prescription drug prices. Rather, it can only review drug prices and assess penalties to manufacturers of drugs that price products above the guidelines. The extent of the penalties depends on the regulatory atmosphere in which the board operates. As is described in the examples discussed below, penalties can range from monetary assessments to a proverbial slap on the wrist.

The foremost example of a price review board in practice is in Canada, where such an entity has existed since late 1987. The Canadian Patented Medicine Prices Review Board (PMPRB) was created in conjunction with provisions that increased patent protection for drugs in Canada. Prior to the PMPRB's inception, Canadian patent laws allowed generic manufacturers to sell copies of patented drugs so long as a royalty was paid to the innovative manufacturer. When Canada changed its patent laws to provide a longer period of patent exclusivity, it instituted the PMPRB in order keep prices and price increases on patented drugs from being "excessive". For drugs that offer substantial therapeutic improvement over existing products, the PMPRB defines an excessive price as a price that exceeds the prices of drugs in the therapeutic class and the median of prices in seven other industrialized countries⁷. For other new products, it defines "excessive" prices on new products as a price that bears a "reasonable relationship" to prices of similar medicines (with the definition of a "reasonable relationship determined by the Board). Price increases are considered excessive if the rate of price increase since the date of introduction, or over the last three years (whichever is shorter) exceeds the increase in the CPI over the same period.⁸ The PMPRB cannot set prices, but can assess fines against firms that continue to charge excessive prices (GAO, 1993b; Shulman, 1994).

In general, the PMBRB achieves a high rate of compliance with its guidelines. Of the 79 patented products introduced and reviewed by the Board in 1994 (out of 81 patented products introduced that year), all but 66 (83.5 percent) were launched at prices that fell within the Board's guidelines. Of the 793 existing products with pricing periods ending December 31, 1994, the prices of 781 (98.5 percent) were judged to be within the Board's guidelines (Patented Medicine Prices Review Board, 1995).

A separate issue from compliance is whether prices are lower than they would be in the absence of the Board. A 1993 analysis of the PMPRB suggest that the Board has been effective at restraining price increases in Canada, but that its effect on new drug prices is less definitive. Furthermore, the Board did not prevent increases in either average drug prices nor total drug expenditures, due to high costs of new drugs and increases in drug utilization (GAO, 1993b). This trend has led to continuing high costs of prescription drugs for both public and private payers (Green Shield Canada, 1994).

⁷ Those countries are France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.

⁸ In addition, the annual price increase cannot exceed 1.5 times the growth in the CPI.

A variant of the Canadian price review board was contained in the Clinton Administration's 1993 health reform proposal. The board in the Administration proposal would have jurisdiction only over breakthrough drug products, which are defined as drugs that offer a significant advance over existing therapies. Other patented drugs would not be subject to the board's review. The board would set standards to determine whether the launch price of the drug was "reasonable," but would have no legal power to influence drug prices. (CBO, 1994).

While there is no evidence on the impact of a drug price review board on pharmaceutical R&D in Canada, Grabowski and Vernon (1994) evaluated the potential impact of a breakthrough price review board on the U.S. pharmaceutical industry. Using an approach similar to their earlier simulation models, they estimated the net present value (NPV) of products if breakthrough drugs had profits constrained to zero. They found that such a regulation would result in a negative NPV for the average drug, since the breakthrough drugs contribute such a major portion of drug revenues. However, they do not assess the reasonableness of choosing a regulation which would reduce profits on breakthrough drugs to zero, nor do they evaluate the impacts of other regulations.

Price Controls, Profit Controls, and Reimbursement Limits

Price controls have been applied in many countries as a way of restraining the costs of a prescription drugs in their social insurance programs. France, for example, has until recently applied product-by-product price controls on prescription drugs. Germany and Sweden limit the rate at which products can be reimbursed under the health insurance system: while these rates are not as binding as price controls, prices tend to fall to these rates. The United Kingdom does not explicitly control prices on new drugs--their regulations limit the profit that each firm can earn on sales to the National Health Service--but does limit price increases on existing drugs. Each of these countries also controls payments to drug wholesalers and to pharmacists (Gross, et. al, 1994).

Reimbursement controls have also been applied in this country's Medicaid program. Since 1975, the federal government has regulated Medicaid reimbursement through the Maximum Allowable Cost/Estimated Acquisition Cost (MAC/EAC) program, which is used to restrict Medicaid payments to pharmacies. MACs set reimbursement limits for certain multi-source drugs by limiting ingredient reimbursement to the lowest price at which a generically available drug was "widely and consistently available" (Reeder, et al., 1993). For single source drugs (drugs without generic substitutes), Medicaid's payment is limited to the price generally paid by providers for a particular drug in the package size most frequently purchased by providers (National Pharmaceutical Council 1994). Since 1987, states have been given the authority to set their own payment methodologies for these two major drug classifications (Adams, et al., 1994; Reeder, et al., 1993). Although MACs and EACs actually set reimbursement limits to pharmacists, it is assumed that these regulations ultimately affect the prices which manufacturers can charge.

In summarizing the literature on effects of the MAC and the EAC, Reeder, et al. (1993) noted that the government did appear to receive savings from the program, but that there is uncertainty regarding the size of the savings. Administrative costs, in particular, are hard to ascertain. For example, Reeder, et al. cited a 1983 study (Lee, et al.) which found that the MAC reduced drug expenditures by 1%, but the EAC produced little or no savings because the program resulted in offsetting increased dispensing fees. In addition, they found that prices had a tendency to converge closer to MAC levels.

Additional problems with the program involve actually determining the EAC. Acquisition costs are usually based on average wholesale price (AWP), but pharmacists generally receive a discounted price and the diversity of retail pharmaceutical services makes estimating this actual cost difficult (Adams, et al., 1994). In addition, there are substantial inefficiencies in the MAC and EAC price setting process, largely because of time lags in obtaining new price information and other management difficulties (Reeder, et al., 1993).

While the U.S. government has implemented reimbursement limits, it has not used actual price controls. The experience of European government price controls suggest that these measures, alone, are not sufficient to reduce the growth of prescription drug spending. Total expenditures are the product of price and quantity, and drug utilization may be high in spite of, or because of, low prescription drug prices. For example, real drug prices in France fell by an average of 3.1 percent annually between 1985 and 1991, yet France's drug spending grew by 4.7 percent per year during that period (the same rate of growth as in the United States, where inflation-adjusted prices grew by almost 4 percent per year.). Much of France's drug expenditure growth is attributable to the increase in drug utilization, which grew over 8 percent per year between 1985 and 1990.

Furthermore, price controls may have negative impacts on pharmaceutical R&D. GAO (1994a) analysis suggests that pharmaceutical R&D expenditures are inversely related to the average drug price level in a country, although the magnitude of the relationship is hard to ascertain. In addition, the type of price control may affect the type of R&D that takes place. Studies of factors affecting pharmaceutical R&D suggest that firms' development decisions will reflect the rewards offered by the reimbursement system in the home country. Thus, in France, where drug reimbursement is relatively low and product approval is relatively time consuming, manufacturers put a greater emphasis on developing imitative drugs than on developing therapeutic improvements.⁹ By contrast, firms based in the UK and the United States--both countries where new products can receive high drug prices--have more development of products that offer major therapeutic advancements (Redwood, 1993; Thomas, 1993). Thomas notes that France and the United Kingdom had the same level of pharmaceutical R&D expenditures between 1965 and 1985, but that only 13 percent of the French drugs were products that were innovative

⁹ Drugs entering the French market are reviewed on the basis of price as well as on safety and efficacy (Pelc and Castan, 1994). Because these reviews are performed sequentially, the price review can delay market entry.

drugs intended for the global market, while more than half of the British drug products were globalized.¹⁰

Market Based Approaches

Market based approaches rely on natural market forces, as opposed to regulations, to control drug costs. These policies are the furthest removed from the level of consumption. The market based approaches are based on the idea that if excessive profits exist, competition and market entry will drive costs and profits down. Market based approaches include policies which promote direct competition, pharmacy benefit managed care, and cost-effectiveness studies.

Promoting Direct Product Competition

Encouraging price competition between similar products is the primary market-based policy for reducing the cost of a prescription drug benefit. A prominent example of such a policy is the government's easing of approval requirements for generic drugs. Since 1984, the Food and Drug Administration (FDA) has allowed generic drugs on the market without requiring independent tests of safety and efficacy; generic manufacturers need only show that the generic drug is bioequivalent to the pioneer product (Frost & Sullivan, 1994). This policy has led to substantial growth in the use of generic drugs, which are typically sold at prices that are at least 30 to 50 percent below the brand name price. Generic drugs have risen from about 15 percent of the market (in terms of number of prescriptions) in 1983 to a projected 50 percent in 1995 (Boston Consulting Group, 1993).

Competition can also come from similar innovative products. While such price competition was not prevalent in the past, increases in drug costs and the growth of third-party pharmaceutical payment since the 1980s has led to increased vigilance of drug prices and spending levels. Third party payers--particularly hospitals, managed care organizations, and pharmacy benefits managers--have used product competition to seek price discounts from manufacturers (Boston Consulting Group, 1993). More recently, they have been seeking evidence of cost-effectiveness of medications.

Price competition has been promoted in several ways. For example, in the United States, managed care organizations and pharmacy benefits managers have developed a series of incentives for both physicians and patients to choose less expensive products. These measures include requiring generic substitution; increasing cost sharing on non-generic products; providing physicians with pricing information such as relative price lists; establishing drug formularies; and negotiating prices with drug manufacturers (Boston Consulting Group, 1993). To an increasing extent, these organizations are basing product reimbursement policies on cost-effectiveness criteria. Some PBMs have entered into risk

¹⁰ Because Medicaid pays for a much smaller share of national drug sales than do national health insurance systems, such as those in France and Germany, the effects of Medicaid reimbursement limits on pharmaceutical R&D should be relatively less than in those countries.

sharing agreement with drug manufacturers under which all drugs in a given therapeutic category will be supplied by the manufacturer in return for a negotiated reimbursement rate per member.

Different menus of policies have been applied in the European and Canadian social insurance systems. Physician budget targets, applied to individual practitioners, have been used to try to reduce drug spending in the United Kingdom since 1991 (Gross, et. al, 1994) and were recently adopted in France (Redwood, 1994). Another measure to promote price competition is differential copayments which vary with product price. For example, if a beneficiary in Ontario's drug benefit program is prescribed a drug that has generic substitutes, he or she can obtain the drug without making a copayment if the lowest-priced generic drug is purchased. But if the beneficiary wants a higher priced generic or brand name drug, then he or she must pay the difference between the product cost and the lowest generic price (GAO, 1992). In Germany, the social insurers limit the reimbursement rate for prescription drugs that have generic or therapeutic substitutes. These limits, known as *reference prices*, set the reimbursement rate at roughly the average price of all similar drugs. Consumers must pay the difference between the product cost and the reference price. Sweden also has a reference price system that relates the reimbursement rate to generic drug prices (Gross, et al., 1994).

There has been little study of the impact of increasing generic substitution or increased use of managed care on the cost of a prescription drug benefit or on total health care costs. This is particularly true for examining the impact of foreign programs, although a steep decrease in prices of drugs under Germany's reference price system was observed after that system was implemented (GAO, 1994a; Green, 1994).

One exception is a recent study by KPMG Peat Marwick (1994). This study estimated the cost of a universal prescription drug benefit, similar to President Clinton's health reform proposal, under different estimates of generic drug utilization rates. KPMG estimated that a universal drug benefit would cost \$67.6 billion in 1998, assuming currently projected levels of generic drug utilization. KPMG estimated that incentives in the proposal increasing the rate of generic substitution would result in a \$7 billion reduction in total prescription drug costs, or a total of \$60.6 billion¹¹. They also estimated that more stringent generic substitution requirements would lead to a reduction in benefit costs ranging from \$54 billion to \$58 billion.

While the use of less expensive drugs--particularly generic drugs--can reduce the cost of a prescription drug benefit, its potential for reducing prescription drug benefit

¹¹ In deriving these estimates, KPMG adopted assumptions about the size of the generic market that were consistent with those used by the Congressional Budget Office in estimating the cost of a universal prescription drug benefit. Specifically, KPMG assumed that provisions in the HSA moving more people into managed care and encouraging generic utilization in a Medicare prescription drug benefit would lead generic utilization to reach 26 percent of total prescription drug expenditures in 1998. Current levels of generic utilization, projected to 1998, were estimated to be 12 percent of total prescription drug expenditures.

costs is limited by the extent to which these drugs are used. There is some evidence that, at least through the 1980s, drug prices were not a factor in physician's prescribing decisions. Temin (1980) found that physicians typically did not have information on drug prices and were therefore poorly informed to make choices about relative drug values. Masson and Steiner (1985) observed that physician's decision to prescribe the generic version of a drug was largely determined by whether the physician's prescription pad made permitting or excluding generic substitution the easier course of action. Caves, et. al. (1991) observed a drop in the share of total prescriptions written generically between 1980 and 1989--even though generic substitutes were more widely available during the latter period.

Furthermore, generic drugs have limited use as a cost control vehicle, mostly because these products are available only after the originator drug's patent has expired. Typically, patent expiration can occur as much as 7 to 12 years after the product has been introduced, thereby limiting the ability of consumers to obtain low prices (CBO, 1994).

The reliance on price competition also has the potential to reduce the returns to pharmaceutical R&D and, therefore, new drug development. Grabowski and Vernon (1984) designed a complex model to simulate the impact of greater generic substitution on new drug development. They found that mild generic substitution (defined as 10 percent market penetration) had little effect on their forecasts of new chemical entities (NCEs) developed or on net revenues. However, when generic penetration reached 50 percent of the market, their model showed a 30 percent drop in the average annual number of NCEs developed, and a 28 percent decline in average net revenues. Interestingly, these effects would be negated by a two year extension in effective patent life, suggesting that the Waxman-Hatch Act had negligible effects on the revenues of innovative drug manufacturers. Whether the R&D impacts of price competition are more severe than price regulation depends on the stringency of those price regulations. Clearly, the expanded use of price competition in the pharmaceutical sector can be expected to reduce a manufacturer's expected revenues and therefore a drug's expected returns. In particular, the market may not support as many close competitors in a therapeutic class, so R&D on "me-too" products could decline. In addition, returns to pioneer drugs may also decline in reaction to an expectation of earlier price competition than might occur otherwise (OTA, 1993). However, this decline may be less severe than a policy that regulates all drug prices, depending on the severity with which those controls are applied.

Cost Effectiveness Studies

Cost-effectiveness studies involves the use of economic analysis to rank the desirability of using alternative medical interventions. Typically, these studies involve the comparison of the incremental costs and outcomes treatment to alternative (or most commonly used) set of treatments (Garber and Phelps, 1995). Information gathered by cost-effectiveness studies is used by public and private health insurance authorities to establish coverage and reimbursement policy; by health care providers to evaluate

alternative drug interventions; and by drug manufacturers for pricing guidelines (Luce and Simpson, 1995).

While pharmacoeconomic studies have not been a basis for drug reimbursement in the United States, they are being used for evaluating reimbursement decisions in other countries, most notably Australia and Canada. However, their use is hampered by the lack of established and accepted guidelines for performing these studies. As a result, these countries have established or are establishing guidelines and protocols for conducting cost effectiveness studies.

Australia was the first country to develop and implement guidelines for the economic evaluation of pharmaceuticals. Draft guidelines were released in 1990, revised in 1992, and are currently going through the process of a second revision. Australia has a two-tier system of drug regulation to which the guidelines are directly tied. The first tier is the approval of a prescription drug for marketing by the Therapeutic Goods Administration (TGA) and the Australian Drug Evaluation Committee, which is the Food and Drug Administration's Australian counterpart. Drugs passing the first tier are subject to the second tier, which is a consideration for reimbursement under the government's Pharmaceutical Benefit Scheme (PBS), which pays for over 90% of outpatient prescriptions. To receive reimbursement, manufacturers are required to provide cost-effectiveness studies that conform to the broad guidelines established by the government. These guidelines address the types of data that should be included, alternative ways of measuring outcomes, and types of analytical techniques that can be applied. (Harris, 1994; Commonwealth Department of Health, 1992)

The use of cost effectiveness studies and guidelines in Canada are less developed than in Australia. Although there is an extensive set of guidelines in existence today, there are no formal groups or agencies that are responsible for either performing the pharmacoeconomic studies outlined by the guidelines, reviewing and valuing different studies, or even housing all studies performed. The guidelines are simply suggestive and are not part of a formal system as in Australia. Studies are intended to inform decision making, not replace it. The guidelines tell how and under what circumstances a pharmacoeconomic study is to be performed, but there are no specification of when the studies should be performed. As time goes on, however, it is likely that Canada will require pharmacoeconomic analyses to be performed in order to accept formula listing and/or reimbursement (Canadian Coordinating Office for Health Technology Assessment, 1994).

Overall, the methodology development for determining cost effectiveness is still in its early stages. Much of the literature has focused on the appropriateness of various evaluation techniques. Economic evaluations are intended to lead to better value-for-money decisions, and more efficient resource allocation. Measuring value-for-money is a crucial part of cost effectiveness studies, but is not easily accomplished. According to Drummond (1994), while a number of methodological issues remain unsolved, current

pharmacoeconomic techniques represent significant improvement to other approaches to resource application.

Use of Managed Care Approaches for Pharmacy Benefits

Another market based option for controlling prescription drug expenditures is the use of pharmacy benefit managers (PBMs). Pharmacy benefits managers are entities that apply managed care principles to administer pharmacy benefits for third-party payers. Typically, PBMs use managed care principles to offer reduced prescription drug costs to third-party payers. PBMs have a wide client base, including health maintenance organizations, Blue Cross-Blue Shield insurers, large companies that self-insure, and federal and state government health benefit programs. Services provided by PBMs range from the design of prescription drug benefits, to the implementation of specific cost containment programs, to simply processing claims without the use of any specific cost control regimen. PBMs are able to enforce individual formularies and DUR, in an attempt to limit costs while providing quality services. Managed care pharmacy programs have claimed cost savings ranging from 30 to 40 percent (Navarro, 1994).

The reported success of managed pharmacy benefit approaches, along with pressures to constrain expenditures, have increased the use of PBMs by third party payers. PBMs covered an estimated 65 and 100 million lives in 1994 and provided payment for 25 percent of the outpatient prescription growth (Mandelker, 1994; Glaser, 1994). This level is expected to increase to 85 percent by 1997 (The Pink Sheet, 1995). Currently, PBMs do not play a major role in the Medicaid market, but some enrollees in Medicaid managed care organizations may have a managed pharmaceutical benefit.

Despite their growing use, many concerns over pharmacy benefits management have been voiced. Representatives of the retail drug industry contend that low fees that PBMs pay to pharmacists may reduce patient access to drugstores. Some physicians have questioned whether managed care approaches restrict the ability of physicians to treat patients with the appropriate medication. Another criticism of PBMs is that they reduce the ability to provide cost effective medical treatment since they manage the pharmacy benefit without considering the effects of decisions on other medical costs. Finally, a concern exists about conflicting interests involved with the ownership of PBMs by drug manufacturers. Since mid-1993, three of the largest PBMs, representing about two-thirds of prescription paid by PBMs, have been purchased by pharmaceutical firms (Ethridge, 1995).

CHAPTER 4

CONCEPTUAL MODEL OF THE PHARMACEUTICAL MARKET

Introduction

This chapter develops a conceptual model of the pharmaceutical market that can be used to analyze the impact of various prescription drug payment reforms. This model incorporates the concept of a pharmaceutical industry with several components: multi-firm drug manufacturers that operates as price discriminating monopolists, charging different prices to different market segments; generic drug manufacturers that operate in a mode which is closer to perfect competition than to monopoly; consumers who purchase drugs from retail pharmacies; institutional buyers that are able to negotiate lower prices for drugs; and government as a payer of drugs. The model allows us to examine the impact of a wide variety of federal drug payment policies on different products sold by a single firm; on different types of firms; on different types of consumers; on the level of competitiveness within the market. It also provides the opportunity to provide a short- and long-run analysis of policy impacts.

The model, to a large extent, is based behavioral assumptions about the pharmaceutical industry that emerge from existing literature. This literature is reviewed in the first section of this chapter. In addition, the model incorporates evidence from Chapter 3 regarding the market's response to drug payment policies.

Background On The Market For Prescription Drugs

Prescription drugs, both for inpatient and outpatient use, account for an estimated \$82.5 billion in sales in 1994.¹ For the most part, these sales accrue to research-intensive producers of innovative drugs. Innovative drug firms not only manufacture drugs for current consumption, but also are the firms that develop new therapies for treating illness and disease. Innovative drug manufacturers traditionally have had the lion's share--about 90 percent or more--of the business in this market.

The remaining share of the market is for generic drug manufacturers. Generic drug companies traditionally manufacture products that are bioequivalent to products sold by the innovative manufacturers. Generic products cannot be sold until after the patent on the originator product has expired. Once on the market, they are typically sold at prices that range from 20 to 90 percent below the brand name price. Generic drugs have been capturing an increasing share of the pharmaceutical market, rising from 15 percent of prescriptions in 1983 to about 40 percent in 1993 (Frost & Sullivan, 1994). Once widely differentiated, the distinction between innovative and brand name manufacturers is more blurry today. Many innovative firms have been entering the generic market by producing

¹ This figure is based on IMS America's Class-of-Trade Analysis, 1994. *Marketletter*, July 17, 1995, p.15.

their own generic lines. Others have bought generic drug firms or have entered into strategic alliances with existing firms.

Branded and generic drug firms have very different ways of operating and face different types of markets. Innovative firms are often multinational in scope, with manufacturing, distribution, and research and development capabilities throughout the world. They devote a relatively large proportion of sales on research and development.² Firms are able to establish product identification that allows them to separate their products from competitors. By contrast, generic firms operating in the U.S. have largely focused their efforts on the domestic market. Their R&D costs are a much smaller share of sales than they are for the innovative firms. Furthermore, because generic products are bioequivalent to one another and to the innovative product, it is hard for a manufacturer to distinguish the product on grounds other than price.

Within the innovative drug industry, an additional distinction can be made between the traditional pharmaceutical industry and the emerging biotech companies. Traditional pharmaceutical manufacturers are more established, have a wider product line, and are able to fund R&D from internal sources. Today's research-based pharmaceutical industry can be traced to the mid-1930s. Before this period, the drug manufacturing business was noted by the production of a limited number of well-known products and a product portfolio that changed little from year to year. But with the medical and commercial success of the newly developed antibiotic sulfanilamide, and later of penicillin, drug manufacturers realized that new drug development would be the key to future success. R&D by these drug manufacturers led to the introduction of over 1,200 new chemical entities between 1946 and 1991. (See Egan, et al., 1982; Comanor and Schweitzer, 1995).

By contrast, the emergence of biotech drug manufacturers is a relatively new phenomenon. Development of this area has evolved as a result of recent scientific advances in human gene research. Unlike the traditional pharmaceutical industry, most of the biotech companies are start-up companies. While some have been successful with product introductions, few have products currently being marketed. As with the distinction between the innovative and generic industries, the distinction between biotech and traditional pharmaceutical manufacturers may become blurred over the years as biotech manufacturers enter into strategic partnerships with the traditional drug manufacturers.

U.S.-based pharmaceutical manufacturers lead the world in drug sales and in the development of innovative drugs. The United States is the home to the largest market, with about 27 percent of prescription drug consumption among OECD member countries (Comanor and Schweitzer, 1995). U.S.-based firms account for 113 of the 265 major globally prescribed drugs that were developed between 1970 and May 1992 (Redwood,

² The Pharmaceutical Research and Manufacturers of America estimates that pharmaceutical R&D will average 19.9 percent of sales in 1995.

1993).³ By 1991, member firms of the Pharmaceutical Manufacturers Association (now the Pharmaceutical Research Manufacturers of America) reported spending \$8.9 billion for research and development, of which 82 percent was spent in the United States (Comanor and Schweitzer, 1995).

The pharmaceutical industry is noted by high profits and high risks. A number of studies have shown that annual rates of return in the pharmaceutical industry are two to three percent above the average for all industries, even when accounting for the pharmaceutical industry's higher level of intangible capital.⁴ A study by the Office of Technology Assessment concludes that each new drug introduced in the U.S. market between 1981 and 1983 (the last year for which data were available) returned about 4.3 percent of the price of the drug, on average, over its product life. Early years' sales revenues were higher for drugs approved for marketing in the period 1984-88 than did the 1981-83 cohort during the early years of approval.

Continued innovation and introduction of new products is key to the success of drug companies. While most companies have a diversified product line, many receive the bulk of their revenues from only a few products.⁵ But these drugs have a limited life span in terms of the revenue stream that they will provide. For example, Grabowski and Vernon have estimated that the effective patent life for newly introduced drugs is between 9 and 13 years, after which revenues drop off in response to generic competition. Drug

³ The leading role of U.S. firms in pharmaceutical development stands aside stringent drug approval regulations that, according to some drug manufacturers, add unnecessary costs to drug development. However, at least one observer of the pharmaceutical industry suggests that the long approval process actually led to the development of a more research intensive pharmaceutical industry in the United States. Thomas (1993) contends that the FDA's rigorous approval process too costly for smaller firms, and that it rewards larger firms that can support the development of drugs that are more costly but also provide more significant benefits.

⁴ A number of researchers have suggested that accounting measures of profit overstate the actual profitability of the pharmaceutical industry. These critics assert that accounting measures of profit overstate true rates of return because they do not capture the effect of the industry's high level of intangible capital, relative to other industries. This assertion is supported by Clarkson (1993), who found that the pharmaceutical firms were among the leaders in spending (as a share of net sales) on two key elements of intangible capital--R&D and marketing. Clarkson also argued that R&D in the pharmaceutical industry translates into products at a slower rate than in other industries. Adjusting for different rates of investing on intangible capital for 113 firms in 14 industries, Clarkson estimated the pharmaceutical industry's annual rate of return on capital at 13 percent, compared to an average for all industries of 11 percent. Similar results were obtained in a study sponsored by the Office of Technology Assessment. See Kenneth Clarkson, "Intangible Capital and Profitability Measures: Effects of Research and Promotion on Rates of Return" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993); William Baber and Sok-Hyon Kang, "Accounting-based Measures as Estimates of Economic Rates of Return: The Case of the U.S. Pharmaceutical Industry, 1976-87" (paper produced under contract with the Office of Technology Assessment, July 1991). These issues are discussed to a greater extent in Congressional Budget Office, *How Health Care Reform Affects Pharmaceutical Research and Development*, Washington, D.C., June 1994.

⁵ Many drug companies relied on just three products for the bulk of their 1992 revenues. Seven of the companies listed received more than half their 1993 revenues from three drugs (CBO, 1994; Boston Consulting Group, 1993).

manufacturers must have a stream of drug in development in order to produce new drugs that, if proved to be marketable, can replace revenues lost by the patent expiration of leading products.

The volatility of firms' standings among the top manufacturers within the pharmaceutical industry suggests that the industry is not dominated by just a few firms. A study cited by the U.S. International Trade Commission (1991) showed major movement in the ranking of the top revenue earning pharmaceutical manufacturers between 1970 and 1991. Four of the top 15 companies in 1989, including two of the top four, were not among the top 15 in 1980. Six of the top 14, including 1989's leading drug manufacturer, were not among the top 15 in 1970. In examining the changing focus of R&D activities, a 1992 ranking of the top 35 therapeutic categories under development in the pharmaceutical industry worldwide reported nine categories--all in biotech and immunological research--that were not even featured among the top categories just five years earlier. Others, such as memory enhancers, anti-anginals, imaging agents, and anti-psoriasis drugs, had risen substantially. Similarly, R&D projects in some categories that had ranked high priority in 1987 had fallen significantly in priority by 1992 (Redwood, 1993).

As new product development is the key to continued success of pharmaceutical manufacturers, pursuit of research and development activities is the key to new product development. But pharmaceutical firms face more difficulties than do other manufacturers in that pharmaceutical R&D is relatively costly, has low probability of success, and is unlikely to produce the kinds of products that will provide blockbuster revenues. A number of studies of the R&D process suggest difficulties in firms' ability to develop new drug entities to replace these products. One of the problems involves the difficulties in getting a new drug to the marketplace. The drug development is quite extensive, involving discovery of new molecules; exploring the therapeutic advantage of promising compounds; determining how to get a compound into a form for human use; conducting safety testing. In addition, the process involves extensive clinical evaluation on both animals and humans which must be overseen by FDA. Only 1 of every 1,000 chemicals ever tested eventually makes it through this complex process and onto the market, after an average of 12 years of development and testing. (OTA, 1993).

In addition, the cost of developing drugs is high, although the actual cost of bringing a new drug to market is hard to estimate because many R&D efforts cannot be assigned to a single product. Two studies have estimated the cost of bringing a new chemical entity to the market. Hansen (1979) examined costs for a sample of NCEs that first entered human clinical trials from 1963 to 1975, while DiMasi, et al. performed a follow-on study of 93 NCEs first undergoing clinical trials between 1970 and 1982; both studies were reviewed by the U.S. Office of Technology Assessment (OTA, 1993). OTA's analysis supported DiMasi, et al.'s finding that R&D costs are increasing over time. Using data from the DiMasi study, OTA estimated the average present value of after-tax cash outlays for new drug development to be about \$200 million (in 1990 dollars). This estimate is sensitive to a number of factors. Drug development costs are

probably lower for drugs offering major therapeutic improvements, since these drugs seem to have a shorter approval process than products deemed to be less important (Dranove and Meltzer, 1994). In addition, the cost of bringing a new drug to market is sensitive to changes in science and technology, shifts in the kinds of drugs under development, and changes in the regulatory environment (OTA, 1993).⁶

Once the drug gets on the marketplace, there is still a risk as to whether it will bring in revenues to the company. Grabowski and Vernon (1990) traced the sales of drugs brought onto the market between 1970 and 1979. They found a skewness in the sales distributions of products, with only 3 in 10 bringing in revenues sufficient to cover the R&D costs of the average pharmaceutical product. Part of this skewness was attributed to the effective patent life of products (the time between FDA approval and the expiration of the product's patent). OTA has shown that the effective patent life for products approved between 1984 and 1989 was 9 to 10 years, compared to about 13 years for products approved between 1968 and 1972 (and about 8 years for products approved between 1978 and 1982). The reason for the differences are : (1) greater length of FDA approval, over time, and (2) patent term extensions, passed as part of the Waxman-Hatch Act, which made new drugs eligible to receive patent term extensions to compensate for regulatory delays in approval. (OTA, 1993, p.83).

The impact of patent expiration on sales is in dispute. Grabowski and Vernon (1995) found that average annual revenues of 14 drugs that lost patent protection was about 43 percent of the revenues in the year before patent expiration. By contrast, OTA found that, for a sample of 35 products, originator drugs maintained a market share of almost 85 percent as long as six years after patent expiration. This sample did not include sales of drugs to hospitals, where generic utilization rates are much higher than in the outpatient sector. Accounting for the hospital sector, OTA estimated that originator revenues fall to 66 percent of market share in the four years after patent expiration, and 60 percent in the six years after patent loss. OTA also noted that some firms react to patent expiration by developing an extension of the product, such as an extended release version of the drug. Because this new drug has patent protection, the firm can direct marketing efforts away from the product with generic competition and towards the product extension.

The amount of R&D in which a drug manufacturer will engage is a function of the expectations that the firm has about the potential revenue for its product as well the costs of R&D. Early in the development process--as much as 10 to 12 years before the drug reaches the market--drug manufacturers must evaluate the competitive structure of the market. This process involves making assumptions about whether competing therapies will have reached the marketplace as well as assumptions about factors affecting the competitive determination of drug prices in the market. While some analysts have suggested that the pricing system in a market or country is a strong determination of the

⁶ There is a wide variation in development costs for different types of drugs. For example, DiMasi, et. al. (1995) estimated that clinical period costs for approved NCEs ranged from \$7.1 million for topical steroids to \$66.7 million for cardiovascular agents (1993 dollars).

success the pharmaceutical industry in that market (see, for example, Redwood 1993), other evidence suggests that prices are but one factor affecting pharmaceutical R&D.

In general, countries with the most pricing freedom had the most developed pharmaceutical industry, with a high number of innovative drug products. In countries with relatively low drug prices, domestically-based drug manufacturers are observed to concentrate less on innovative products than on imitative products because the financial reward for developing an innovative drug is low (Redwood, 1993). For example, between 1965 and 1985, French drug manufacturers, located in a market where government regulation kept prices low, produced 204 new chemical entities, of which 26 were considered global and 120 were considered local products. Total drug R&D spending was roughly the same in the United Kingdom during those years, with 84 new chemical entities introduced. However, in the U.K. market, where firms have more freedom to set launch prices, 43 were considered global and only 21 were considered local (Thomas, 1993).⁷

But while pricing freedom and price levels may be important determinants for deciding where pharmaceutical R&D will be performed, they are not the only considerations. For example, Canada has among the world's highest prices for prescription drugs, but has virtually no innovative drug R&D, while such industries thrive in Britain and Sweden, which have lower prices (GAO, 1994). Canada's low drug R&D is likely attributable to weak patent laws that were in effect until 1993, which decreased the incentive to develop a drug in Canada.⁸ Patents are just one of many factors that affect where firms perform pharmaceutical R&D and what level of funds are invested. Among the other factors affecting pharmaceutical R&D are:

- R&D and marketing infrastructure. Successful R&D requires the scientific and technical base to perform such studies, as well as physical facilities.
- Government funding of R&D. Government support of basic or disease-oriented research, such as that provided in the United States by the National Institutes of Health and the National Science Foundation, provides both financial and (perhaps more importantly) a scientific support for a domestic

⁷ Thomas contributes the difference in rates of product globalizability to the degree of concentration of pharmaceutical R&D. He notes that concentration of a small number of products in a handful of pharmaceutical firms, such as occurs in the United States and the U.K., contributes to success in the world market. By contrast, the spreading of R&D on a large number of minor derivative products discovered by many weak firms, as occurs among French and Japanese pharmaceutical firms, has led to what he terms as "competitive failure".

⁸ Until 1993, manufacturers of generic drugs in Canada could manufacture a patented drug by obtaining a compulsory license from the Commissioner of Patents. The compulsory license allowed the licensee the right to produce the patented drug in return for a royalty paid by the generic manufacturer to the patent holder. From 1969 to 1987, compulsory licenses could be obtained at any time. From 1987 to 1993, patented products received seven years of market exclusivity (ten years if the drug's active ingredient was imported). Changes in Canadian patent law restricted the issuance of compulsory licenses after 1993 (GAO, 1993).

pharmaceutical industry. In the United States, federal government support for medical research exceeds that allocated by other national governments.

- Size of the domestic market. While not all drug manufacturers receive the bulk of their revenues from their home market, a substantial home market will provide a broader base from which to earn revenues and recover R&D costs. The size of the domestic market will depend on population, income levels, extent and type of third-party coverage, and prescribing habits of physicians.
- Strong overseas presence. Some studies have found that companies that are globalized are stronger R&D performers. Thomas (1989) asserts that the ability to compete successfully in international markets depends largely on the degree of competition in the company's home market. Thomas goes on to suggest that the level of competition at home depends on rigorous quality restrictions on market access, high levels of publicly funded biomedical research, and unregulated domestic prices.⁹
- Length of drug approval process. Long drug approval will add costs to the development stage and, depending on the country's patent laws, take away time from effective patent life. However, stringent drug approval requirements could provide a competitive advantage by signaling safety and efficacy. If prices must also be approved, then additional delays further devalue the product's market worth.
- Product liability laws. Some industry sources have suggested that stricter product liability laws in the United States place U.S. firms at a competitive disadvantage and therefore stunts domestic innovation, especially in high-risk areas such as obstetrics and birth control.¹⁰

For a discussion of these issues, see Egan, et al., (1982); ITC (1991); Pollard (1993); OTA (1993); and GAO (1994).

Structure Of Demand For Prescription Drugs

As with most health care services, the demand for prescription drugs operates differently than the standard demand for a commodity. In most markets, demand is influenced by the ability of consumers to choose between commodities. It is generally assumed that consumers can compare between substitute commodities, and that they--rather than some other party--make the ultimate decision about which commodity to buy and how much will be purchased. Furthermore, it is typically assumed that consumers pay

⁹ Lacy Glenn Thomas, "Spare the Rod and Spoil the Child: Vigorous Competition and Vigorous Regulation Promote Global Competitive Advantages, unpublished manuscript, October 1989; cited in U.S. International Trade Commission (1991).

¹⁰ While non-U.S. companies operating in the United States face the same risk of product litigation, they typically have less exposure than U.S. firms because only their U.S.-based assets can be seized.

for the good from their own resources, so that the price of the commodity becomes a primary factor in deterring how much of will be purchased.

In many ways, the market for prescription drugs does not conform to these conditions. First, the nature of prescription drugs means that consumers often do not have a choice about what product will be prescribed. These decisions are made by the physician, who typically knows more about the appropriate product than does the consumer. Unlike the consumer, who is concerned with the amount that he or she will have to pay for the product, the physician may be very concerned with the efficacy of the drug but have little concern with its costs.

A second contributor to market failure is that consumers may lack information that allows them to choose between competing therapies. Even when less expensive products are available, consumers may be reluctant to use them. For example, some consumers opt not to buy less expensive generic substitutes because of a perception that these products are of an inferior or uncertain quality.

Third, many consumers are insulated from the cost of prescription drug coverage by the presence of health insurance. While consumers pay a higher share of costs out-of-pocket for prescription drugs than for physician and hospital services, health insurance still a large and increasing share of prescription drugs. Consumer out-of-pocket costs prescription drugs have fallen from about 75 percent of outpatient prescription drug costs in 1977 to about 60 percent in 1991.¹¹ The presence of health insurance reduces the price paid by consumers and, therefore, the likelihood that they will respond to high prices by decreasing consumption.¹²

These differences can affect the way that the demand for prescription drugs responds to the presence of high prices or competing products. All of these factors would be expected to reduce the elasticity of demand for prescription drugs relative to what the elasticity would be if consumers were aware of the price and efficacy of substitute goods, if they paid the full cost of prescription drugs, and if the party choosing the product (e.g., the physician) was sensitive to product cost.

Indeed, the empirical evidence of patterns of prescription drug prices suggests that some price trends run counter to conventional economic expectations. For example, economic theory suggests that when a product is introduced to compete with an existing therapy, then the manufacturer would set the new price lower than the originator price in order to attract customers. Furthermore, the producer of the originator product might be expected to reduce its price in reaction to this competition.

There is conflicting evidence about the degree to which physicians are sensitive to the prices of prescription drugs, particularly of complementary products. At least until

¹¹ By comparison, in 1991 consumers paid for 18 percent of physician charges and less than 5 percent of hospital costs. See Levit, et al. (1994).

¹² The type of insurance will also affect consumer demand.

recently, physicians have been believed to be relatively unaware of differences in prescription drug prices. Masson and Steiner (1985), for example, found that the probability of physician prescribing a generic drug was most closely related not to the availability of the drug or its perceived therapeutic value, but to whether the prescription pad made including or excluding the generic the easier course of action. Caves, et al., (1991) found that in 1989, only 21 percent of multi-source drugs (drugs for which generic substitutes exist) were prescribed generically. In recent years, however, physician awareness of pricing is increasing. Part of this change is due to the increased intervention of third-party payers and the use of drug formularies to which physicians must now sometimes refer. In addition, physicians are reporting increasing numbers of patients asking about generic use or about the price of their prescription (Research Institute of Pharmaceutical Sciences, 1995).

At least until recent years, the movement of prices in the pharmaceutical market has been consistent with the hypothesis that competitive forces were not as strong in this market as with other goods. The literature offers contradictory evidence about the behavior of prices. For example, Cocks (1975) and Cocks and Virts (1974) found a general decline in the prices of drugs introduced between 1962 and 1971. Reekie (1978) also found that drug prices declined over time, even as average drug prices were rising (due to the price premium charged to products that offered substantial therapeutic improvements). By contrast, Schwartzman (1976) observed that prices of antibiotics fell after entry by competitors, but that prices remained steady in other therapeutic categories. Bond and Lean (1977) found that prices remained steady for the first seller in two different therapeutic categories that they reviewed. Similarly, Statman (1981) observed that product recognition was a more important factor than price in maintaining market share for the products he examined.

In addition to the issue of price rigidity, some analysts have observed that new products do not always compete on price with therapeutic substitutes. Rather, these new products were often introduced at a premium. According to a study by the Research Institute of Pharmaceutical Sciences (1995), this average premium over the product leader ranged from 20 percent to 77 percent between 1977 and 1992. More recent studies have suggested a partial reversal of this trend, at least for non-generic competitors. For example, the Boston Consulting Group (1993) reported that new drugs introduced between 1991 and 1992 in therapeutic areas where treatments already existed were launched at prices that averaged 14 percent below that of the market leader. The Research Institute of Pharmaceutical Sciences reported that between 1993 and September 1994, new products were introduced at prices below that of the leading competitor, but does not provide information on prices relative to other competing products.

Prices of originator drugs are even more rigid in reaction to the entry of generic competitors. This would be consistent with the hypothesis that firms adopt a “harvesting strategy” in which the manufacturers of originator drugs lose market share, but charge a higher price to that portion of the market that is willing to buy the brand name drug despite the existence of a lower price substitute. A number of studies have documented the trend by which brand name manufacturers segment the market by charging higher

prices to segments of the market that are less price sensitive. For example, Caves, et al. (1991) examined prices of branded drugs that were subject to generic competition between 1976 and 1987. OTA (1993) studied prices of 35 products that lost patent protection between 1984 and 1987. Prices of drugs in OTA's sample increased an average of 69 percent in constant dollars in the six years after patent expiration, while generic prices were only 20 percent of the originator price. OTA's study looked only at outpatient drug prices; originator prices charged to hospitals may have been closer to the generic price. They found that brand name drug companies reacted to generic competition by lowering their prices to the inpatient sector, where buyers would be expected to be more price sensitive, and increasing them in the outpatient sector.

In recent years, there has been a change in the relationship between drug manufacturers and purchasers. One key factor has been partnerships and strategic alliances between drug manufacturers and pharmacy benefits managers. Since late 1994, the three largest pharmacy benefits managers, Medco Containment Services, Diversified Pharmaceutical Services, and PCS Health Systems, have been purchased by major drug manufacturers--Merck & Co., SmithKline Beecham, and Eli Lilly & Co., respectively (Lee and Lee, 1994). Furthermore, some institutional buyers, such as managed care organizations, pharmacy benefits managers, and hospitals, have been entering into non-traditional partnerships with drug manufacturers for providing drugs to their patients. These include medical-based approaches such as disease management, as well as risk sharing approaches such as capitation of payments for particular therapeutic categories. These approaches, which are still in evolving throughout the industry, are changing the way that prices are being set in the industry.

Segmentation Of Payers In The Pharmaceutical Market

Analyses of the prescription drug market suggest that the degree to which competitive forces affects the demand for prescription drugs varies by payer. The pharmaceutical market can appropriately be described as consisting of several distinct submarkets, each of which has different responsiveness to competitive forces. These submarkets can be divided by the setting in which the drug is prescribed and the ability of the third party payer to influence what type of drug prescribed. As is discussed below, there is a significant amount of evidence that the demand for prescription drugs differs between inpatient and outpatient sectors, and in the outpatient sector between managed care buyers and those paying fee-for-service. In addition, because of FDA prohibitions on reselling prescription drugs, these market differences are allowed to persist.

The differences in demand elasticity between the cash-paying outpatients, insured outpatients, and the inpatient sector can be described by understanding the different incentives facing providers and payers in these sectors. In the cash-paying outpatient sector, patients typically receive a prescription from a physician and fill it at a pharmacy. Neither the physician nor the pharmacy has a financial incentive to determine which drug is the most cost effective. Depending on the physician's relationship with the third-party payer, that physician's sensitivity to price may range from being somewhat sensitive to having no sensitivity at all. The physician's prescription is likely to be filled as written,

with the possible exception that a generic drug may be substituted for a brand name prescription.¹³ The pharmacist cannot otherwise override the physician's prescription with a less expensive product (without physician permission), nor can the consumer request a different product from the pharmacist.¹⁴

By contrast, in the inpatient setting, the institution has both the incentive and the ability to reduce the costs of drugs dispensed. More than the independent physician, the institution bears a financial cost of the drugs prescribed. This is because the reimbursement for many patients, such as Medicare patients in hospitals and Medicaid patients in nursing homes, is a lump sum payment which must cover all costs--be they prescription drugs, physician services, or other medical or hotel services. Therefore, the institution is often the ultimate payer for the drug, and has an incentive to induce the physician to choose the least expensive product for treating the patient.¹⁵

Because the payer can influence the decision-maker over which drugs will be used, buyers in the inpatient sector have greater ability to promote consumer use of competing products. This implies that the demand for drugs in the inpatient setting would be more price elastic than the demand for drugs in the outpatient setting, all other things being equal. Indeed, hospitals and nursing homes have been leaders in the development of approaches for influencing physicians and patients to use price as a factor in choosing between similar drugs. Among the measures used in these sectors are the use of drug formularies and price negotiations with drug manufacturers. Through drug formularies, institutions are able to restrict the prescribing of products that are deemed to be less cost effective than competitors, and to provide physicians with information about relative prices of similar products. By negotiating prices with manufacturers, institutions are able to obtain lower prices for products--often in return for agreements to increase market share to those manufacturers that offer the best prices for their drugs. Some institutions have adopted cost-effectiveness approaches, in which the prices that they negotiate with drug manufacturers reflect not only the price of therapeutic substitutes, but also savings that might be achieved in other types of health services by using the particular drug.

For similar reasons, third-party payers that offer an outpatient prescription drug benefit have an incentive to reduce prices. Many of these payers have adopted a managed care approach, in which the payers take a more active role in determining what types of products can be prescribed, analyzing the relative price and efficacy of alternative products, negotiating prices with drug manufacturers as well as dispensing fees for pharmacies, and encouraging wider dispensing of generic drugs. This pharmacy benefits management can be done internally, or can be contracted to an external Pharmacy Benefits

¹³ The pharmacist may have an incentive to dispense a generic version of the prescribed drug if the generic drug has a higher profit margin than the brand name product.

¹⁴ One survey of physicians has found an increasing trend in consumers discussing drug prices with their physicians *before* the prescription is written (Research Institute of Pharmaceutical Sciences, 1995).

¹⁵ Some payers may seek to obtain the least expensive drug, regardless of how the drug's use affects total health care costs. Others may adopt a broader measure of cost effectiveness that measures the entire cost of treating the patient's condition.

Manager (PBM). A PBM typically operates by accepting a capitated fee in return for the provision of prescription drugs for the insured population. PBMs then act as intermediaries between the payer of prescription drugs (i.e., the health insurer), the consumer, and the pharmaceutical company--in effect managing the provision of prescription drugs to the beneficiary or enrollee (CBO, 1994). The PBM may take the role of negotiating drug prices and pharmacy dispensing fees on behalf of the third-party payer, often agreeing to provide all prescription drugs to members for a capitated fee.

HMOs and PBMs are able to reduce costs by decreasing the role of the physician in determining drug choices and increasing the role of the payer. These organizations will often establish formularies that exclude or discourage the use of certain products seen as less cost effective than other products. In addition, the payers often are able to exert a significant amount of market leverage to obtain lower prices from drug manufacturers and pharmacies. Rather than paying a market price for drugs, they can negotiate prices with drug manufacturers, often agreeing to shift market share for specific therapeutic categories in return for discounts or rebates. They can control dispensing by establishing their own pharmacies, or by establishing a network of outside pharmacies where the dispensing fee is negotiated.

Managed care in pharmacy is absorbing an ever increasing share of the pharmaceutical market. In 1980, an estimated 5 percent of the insured population had some sort of managed pharmacy benefits. Walsh America PMSI estimated that 25 percent of the drug market volume was covered by managed care in 1994.¹⁶ One estimate suggests that 65 percent of the population will be covered by a managed pharmacy benefit by 1998 (Mandelker, 1994).

Conceptual Model Of The Pharmaceutical Market

The characteristics of the pharmaceutical industry described in the preceding section provides the basis for the development of the conceptual model of the pharmaceutical industry. This model is presented in three parts. The first part will introduce the submodel of the pharmaceutical firm, focusing on what affects the supply of pharmaceuticals. This is followed by a presentation of the model of the demand for pharmaceuticals, with particular emphasis on the submarkets by different types of buyers. The third component discusses factors affecting the future supply of pharmaceuticals by modelling determinants of manufacturers' R&D activities.

Model of the Pharmaceutical Manufacturer

Our model of the pharmaceutical manufacturer adapts an approach developed by Cocks (1992), who in turn applied Clemens' (1958) model of the multi-product firm to the pharmaceutical industry. This approach is a Schumpeterian model of the pharmaceutical manufacturer, in that it emphasizes change in the market and the manufacturer's adaptation

¹⁶*The Pink Sheet*, February 13, 1995.

to that change. The model is a dynamic one, in which the market never reaches equilibrium. Rather, it allows for continuous decisions by the pharmaceutical firm that are a result of the firm's research and development activities; other firms' entry in certain product lines; and changes in the nature of the demand for prescription drugs.

Inherent in the model are two basic assumptions about the market for prescription drugs:

1. The existence of price sensitivity by consumers--or their agents--for new and existing drugs, and
2. That R&D serves as the primary catalyst for changes in the portfolio of drugs produced by each firm.

Several assumptions are key to the operation of the model. The first assumption sets the conditions for consumers shifting demand from more expensive to less expensive products when those less expensive products enter the market. If consumers were not price sensitive, then manufacturers would not have an economic incentive for developing lower-priced substitutes to compete against profitable products. The existence of even a limited amount of consumer price sensitivity allows us to assume some degree of competitive pricing by manufacturers. It also provides a rationale for manufacturers losing market share when competitors enter the market with less expensive products. As was discussed in the preceding section, the assumption of price sensitivity is a reasonable one given the behavior of prices over time and the increasing ability of institutional purchasers (including HMOs and PBMs, as well as hospitals and nursing homes) to use the existence of competing products to gain price reductions.

In this model, drug manufacturers are profit-maximizing firms that sell multiple products. It is assumed that there is homogeneity in inputs, in that firms can use the same production processes for several different products--both manufacturing processes (for instance, production of different medicines from the same manufacturing facility) and shifting research scientists from one to another related R&D projects. It is assumed that resources are easily transferable within the firm at least in the medium and long term--an assumption that is consistent with a high cross-elasticity of supply in both production and R&D activities within the chemical industry (Clemens, 1958). This assumption also implies that product output can be measured in terms of the units of inputs employed in production.

Secondly, the model assumes that the market conditions for the various products manufactured by each firm can range from strong market power to pure competition. Manufacturers of products that are pioneers in their class--that is, for which no therapeutic substitute exists--would be expected to be able to exert strong market power. Examples of pioneer products might include AZT for the treatment of AIDS-related symptoms; Tagamet, which was the first H₂ antagonist for the treatment of ulcers; and Imitrex, which is used to treat migraine headaches. Because few, if any, alternative treatments existed for

these products when they came on the market, manufacturers of those products had market power as the sole producer of the product. By contrast, other drugs face much more competitive structures because of the level of substitute therapies that are available. An example of such a product would be an antibiotic or an H₂-antagonist being introduced today. In between these extremes are different levels of competition that are affected by the number of generic and non-generic substitutes for a product, and the willingness of drug consumers or their agents to substitute between one product and another.

A third set of assumptions for the model relate to the structure of manufacturers' cost functions. In the short run, each firm's marginal costs are assumed to be a low share of total costs and are assumed to be constant over the relevant range of output. The first part of this assumption reflects the fact that many of the costs incurred in drug development, such as R&D and marketing, do not change with the quantity of the product purchased. Comanor and Schwieter report that marginal costs account for only about 30 percent of a product's value. In the long run, however, all drug manufacturing costs are variable. Egan, et al. (1982) assume that the firm's long run average cost curve initially declines sharply until some point of minimum efficient size, and then declines slowly. This assumption reflects the economies of scale of pharmaceutical R&D and marketing that are associated with larger firms.¹⁷ At some point, the average cost curve should slope upward to reflect inefficiencies that can arise from a large and burdensome management structure. However, following DiMasi, et al., we assume that the firm operates in the decreasing part of the long-run average cost curve.

Related to this previous assumption is that firms seek to at least recover long run average costs over time. This assumption implies that, over time, firms must earn sufficient revenues to pay for their R&D costs, whether those costs are financed out of their own financial resources (as occurs for many traditional pharmaceutical manufacturers) or from equity or debt financing (the alternative chosen by most biotech firms). Each firm's current portfolio of products finances the development of future drugs because of the long length of time before products currently under development will be able to earn revenues. Firms with high-priced, pioneer products are more likely to be able to recover the costs of future innovative investments than firms whose portfolio consists largely of older drugs with many substitutes.

Finally, the model assumes that firms enter new markets in order of their expected profitability. Each firm also tries to enhance the profitability of its products by attempting to establish unique therapeutic value for those products--separating each in some way from the products produced by competitors. The firms try to maximize profitability over

¹⁷DiMasi, et. al. (1995) show that R&D cost per new drug approved in the United States decreases with firm size, while sales per new drug approved increase markedly with firm size. Among the benefits provided by larger firms are the ability to spread out the large fixed costs associated with drug discovery; increased specialization of scientific skills and resources; and regulatory and legal expertise used in the clinical development process; and an ability to pool the risk of unsuccessful R&D efforts over a broader range of potential products.

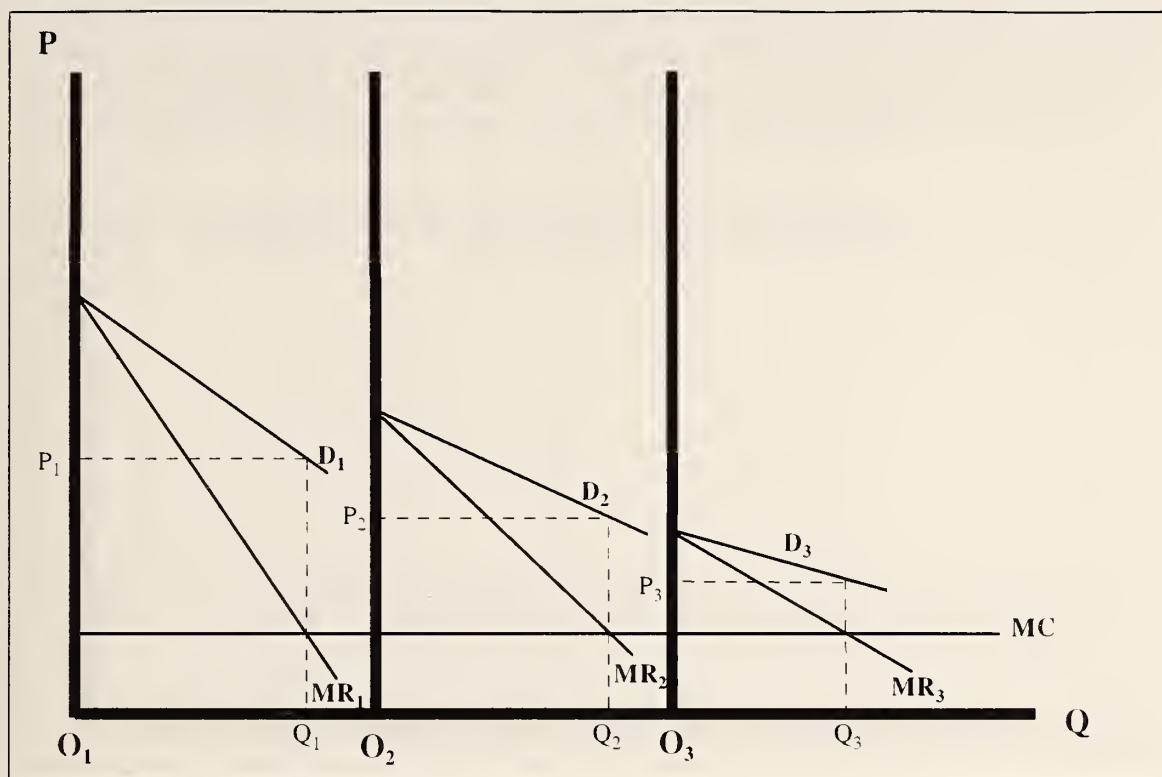
time by dedicating sufficient resources to R&D to maximize the chance of developing pioneer products that bring the most profitability to the firm.

Figure 4.1 presents a diagrammatic exposition of the production decisions made by a particular firm under this model. For simplicity, we assume that the firm manufactures three products. The firm faces separate demand curves for each product, each with its own zero output axis. Note that in this model, there is a single demand curve for each product--it is assumed that either all consumers have the same elasticity of demand or that manufacturers are not able to segment the market by type of buyer. However, the demand curves for each product have different magnitudes and levels of steepness, reflecting the relative importance of each medication or the number of competitors in the market. For example, the demand for product 1, D_1 , is relatively high and steep. In this example, Product 1 may be a pioneer drug in its therapeutic category, or a product that enjoys a particular amount of brand loyalty. Each successive drug has a lower and flatter demand curve, representing decreasing therapeutic value or an increasingly competitive market for those products. Product 3, for example, may be a product for which there are many therapeutic substitutes, or that offers little therapeutic value relative to Products 1 and 2. The manufacturer's optimizing output, in the short run, is determined by equating marginal revenue for each product to the firm's marginal cost curve, MC. In this case, it is assumed that only three products can be manufactured profitably.¹⁸ The equilibrium prices are determined by going up the demand curve for each product.

Figure 4.1 represents the market facing a single firm at a unique point in time. However, the firm continuously has an incentive to develop new products that can bring about additional profits. These products may range from new therapeutic approaches--where no product currently exists--to drugs that are nearly perfect substitutes for existing products and but that can be sold profitably. In between these categories are drugs that offer therapeutic improvements to existing medicines that range from substantial to marginal. The firm has an incentive to develop these products so long as expected marginal revenues exceed marginal costs. Furthermore, firms can, with some constraints, shift production and R&D from less profitable to more profitable areas.

¹⁸In practice, there are conditions under which a manufacturer may sell drugs at a loss. For example, the firm may continue producing product 3 in order to provide a complete product line in a therapeutic category, with the concern that it would lose sales on products 1 and 2 if it could not provide distributors with Product A. For the purpose of this exposition, it is assumed that any sales of products 1 and 2 associated with having product 3 in the line is captured in the demand curve for product 3.

Figure 4.1: Multiproduct Production in Period 1



Like any manufacturer, this firm must earn sufficient revenues over the long term to cover both fixed and variable costs. A large component of those fixed costs are research and development of future drugs--the costs of physical plant, research scientists, and factors associated clinical testing and approval--and advertising and promotional expenses for new products. The magnitude of these costs suggests that a large scale of operations is required for a firm to be able to cover long run average costs from pharmaceutical sales. Furthermore, the average product price must be sufficiently high to cover those costs.

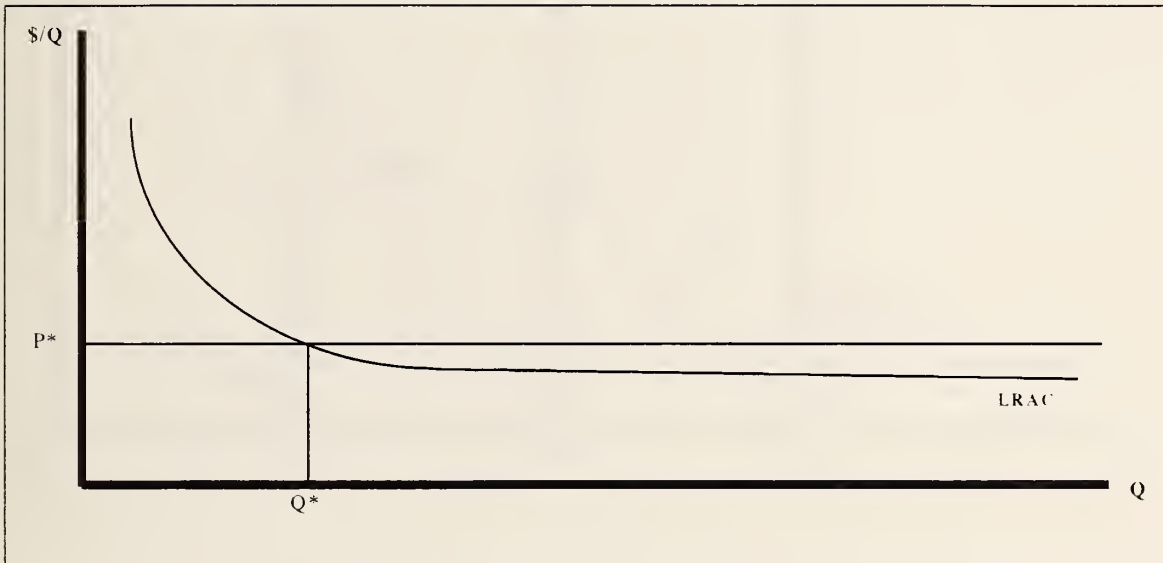
A graphical description of this situation is shown in Figure 4.2.¹⁹ The firm's long run average cost curve, denoted as LRAC, is shown to drop steeply for a given quantity of output, and then fall gradually over a longer range. Its sales revenues are based on the quantity of units sold, Q^* .

In order to show the impact of all product prices on the firm's profitability, we introduce the concept of the firm's "average price" received, which is shown as P^* . The use of this device is intended as an illustrative tool to show the impact of price and revenue changes on long-run profitability of a multi-product firm. The concept of an "average price" reflects an assumption that the firm's products can be grouped into a single market basket. The average price reflects the price of that market basket. For ease

¹⁹ This discussion represents a significant departure from Cocks' model.

of presentation, the average weighted price is assumed to be constant across all quantities. In reality, a firm that is a price discriminating monopolist faces a downward sloping demand curve, and prices fall as quantity increases. So long as the quantity of output in Figure 4.2 is at least Q^* , the firm will be covering long-run average costs. However, if units sold fell below Q^* , then the firm would not be recovering long run average costs.²⁰

Figure 4.2: Long Run Situation of Pharmaceutical Manufacturer



Changes in the Marketplace. At the same time, other manufacturers may be producing products to compete for products sold by this firm. For example, some manufacturers may be readying release of innovative drugs that will compete against highly profitable product 1. Alternatively, a generic manufacturer may be about to release a product that competes against a drug for which the patent is set to expire. These products will reduce the demand for the products currently produced by this firm.

Figure 4.3 shows how these dynamics affect the market within the context of this model. Figure 4.3 shows two specific changes for the firm: (1) the introduction of a breakthrough product which has few substitutes, and therefore a high and fairly inelastic demand (denoted by the curves D_4 and MR_4 at the left of the graph); and (2) a reduction in demand for Product 1, representing the entry of therapeutic substitutes that are produced by competing drug manufacturers.

Figure 4.4 shows potential impacts of changes in the pharmaceutical marketplace on a firm's ability to compete into the future. Figure 4.4 shows two alternate scenarios on

²⁰ In a competitive market, it is assumed that free entry and exit by other firms drive long run economic profits to zero. However, the pharmaceutical industry has substantial barriers that prevent entry by firms seeking to take advantage of economic profits that may exist. Therefore, we assume that it is possible for a firm to earn positive economic profits in the long run, at least for some period during which R&D costs are not fixed.

how these changes could affect a firm. In the first scenario, the loss of markets for product 1 is more than outweighed by the sales of newly introduced product 4. The firm's

Figure 4.3: Multiproduct Production in Period 2

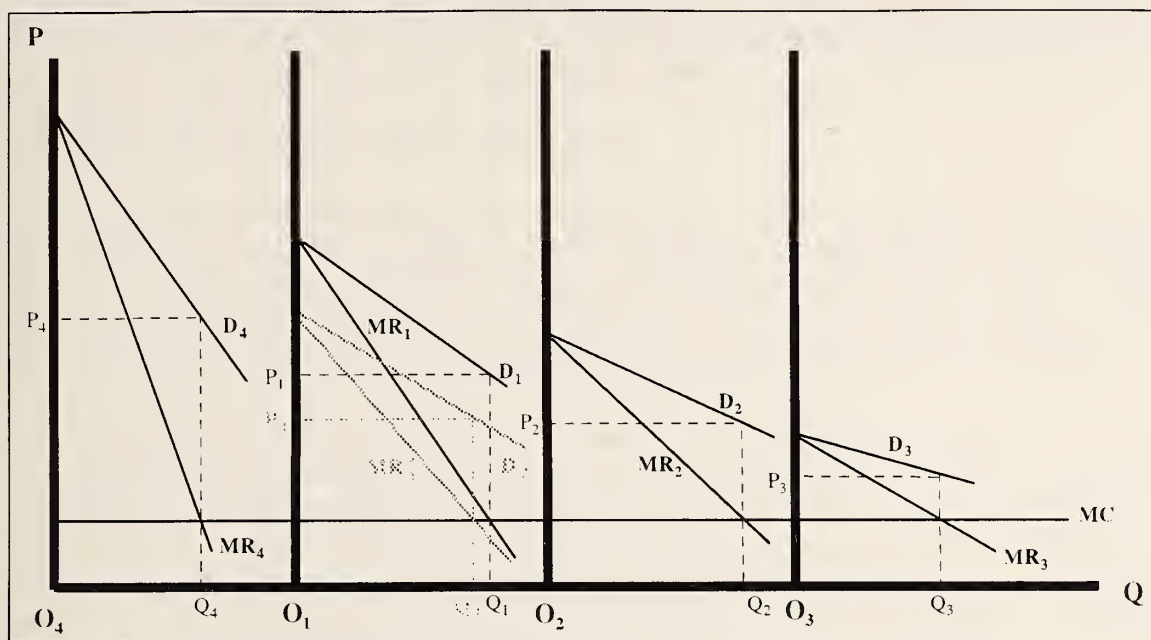
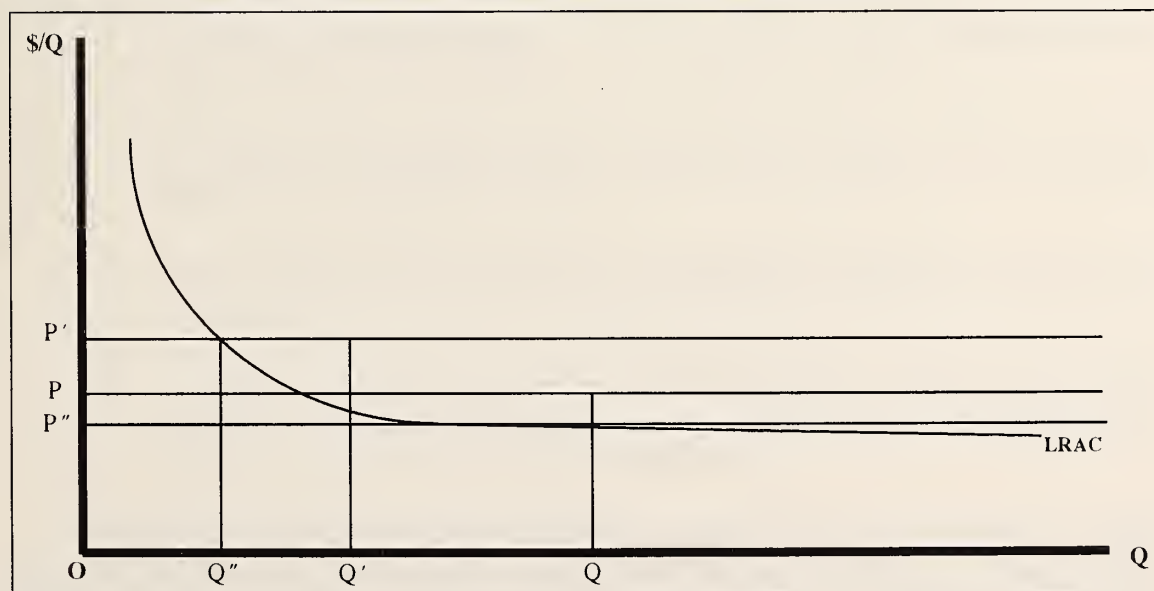


Figure 4.4: Long Run Situation of Pharmaceutical Manufacturer



ability to introduce this drug has raised average price from P to P' , but decreased the quantity of units sold (assuming that product 4 is in a major therapeutic class) from q to q' . Nonetheless, production is still profitable, since $P' > LRAC$ at q' . In the second

scenario, the firm has not produced new products, but its competitors have introduced products that have reduced its market share as well as the price that it can charge for goods. The average price of goods has dropped to P'' , and production has fallen to q'' . The firm is no longer covering long run average costs sufficiently to finance its R&D.²¹ Ironically, the firm now finds it difficult to finance development of products that are sold at higher prices and that can attract a high market share.

Extending Model From One Firm To Many Firms

The preceding discussion shows the dynamics affecting a single pharmaceutical manufacturer. However, the model can be extended to examine the effects of drug policies on the industry by looking at several pharmaceutical manufacturers. This extension will provide the basis for analyzing the dynamics of a changing marketplace on different types of manufacturers -- pharmaceutical and biotech; innovative and generic.

The model presented here is a multi-period model of different types of pharmaceutical manufacturers. For simplicity, it is assumed that there are three manufacturers in this market--two producers of innovative drugs, and one producer of generic drugs. In the first period, the two innovative drug manufacturers -- denoted as Alpha Drugs and Beta Drugs--each produce two patented products. Because both products are under patent, it is assumed that the generic drug manufacturer -- Gamma Products -- does not sell drugs during the first period.

In the next three periods, the introduction of several new products causes changes in the market structure:

- In Period 2, Alpha introduces a new drug that competes directly with an existing product sold by Beta.
- In Period 3, the demand for Beta's existing product reacts to the competition brought about by Alpha's new drug.
- Also in Period 3, Beta introduces a new drug that does not have therapeutic substitutes.
- In Period 4, generic manufacturer Gamma introduces a drug that directly competes with one of Alpha's products for which a patent has expired. This results in a reduction in demand for Alpha's drug.

Figure 4.5 below shows the market for Alpha and Beta in Period 1. Alpha produces two products, which are marketed under the names A and B. Production is limited to these two products because these are the only products which Alpha can

²¹This approach does not require an assumption that firms finance R&D out of retained earnings--the practice used by most traditional pharmaceutical companies. The long run average costs could just as easily reflect the costs of financing R&D externally.

produce profitably during this period. The firm equates marginal revenue to marginal cost for each product, and the price and quantity are determined by moving up the intersection of MR and MC to each product's corresponding demand curve. Similarly, Beta produces products C and BB. Product BB is assumed to be a therapeutic substitute for Alpha's product B, and therefore competes directly with B. This competition results in flatter demand curves for products B and BB than the corresponding products A and C; it is assumed that the existence of a therapeutic substitute makes demand for each product more elastic than is the demand for the sole source products.²²

During the first period, each firm is engaged in research and development activities to enter new markets. It is assumed that Alpha and Beta each earn sufficient revenues from the sales of their products to engage in the R&D required for new product development. It is further assumed that Gamma, the generic manufacturer, is able to attract sufficient capital to engage in product development, either from internal or external sources. These R&D decisions are based on expectations of revenues that can be earned when a product enters the market.

In Period 2, products that were in the development in Period 1 are now assumed to be put on the market. As can be seen in Figure 4.6, Alpha now produces products A, B, and CC--a product that competes directly against Beta's product C. Alpha entered this market under the assumption that it could earn profits by entering the market previously occupied solely by product C.

Subsequently, in Period 3, Beta continues to produce products C and BB, and now also has introduced product E. Product E is assumed to be a single source product and an important therapeutic contribution, so the demand for this product is assumed to be relatively price inelastic. The diagrammatic representation of the changes in the marketplace in Period 2 is shown in Figure 4.7. Note that the introduction of CC by Alpha has decreased--and possibly flattened--the demand for Beta's product C. It is assumed that revenues are sufficiently high for product C for Beta to continue its production during this second period.

Finally, in Period 4, the generic manufacturer, Gamma Drugs, has in the second period introduced a generic substitute to Alpha's product A. This product, AA, is assumed to be issued at a price which is substantially below Product A's price and attracts a substantial share of Alpha's previous market for Product A. As shown in Figure 4.8, Alpha now faces a reduced demand for product A. It is also assumed that the consumers who continue to buy product A are a more price insensitive share of the market (since they

²² Note that there is no reason, *a priori*, for this relationship to always be true. There are conditions under which the demand for product A or C could be more price elastic than for the multiple source products. For example, if product A is relatively expensive, or if it treats a relatively minor ailment (for instance, pain relief rather than hypertension), then consumers may be more sensitive to the price of A than B even if B faces competition. Alternatively, the consumers who purchase B instead of BB may be those who are price insensitive and are attracted to product B rather than BB because of brand loyalty or a perception that the drugs are not interchangeable. For the purpose of this example, we are assuming that none of these conditions apply. Applying these conditions does not alter the analysis presented.

are willing to buy it when less expensive bioequivalent products are available). This assumption is reflected in the steeper demand curve for product A than in the first period.

Figure 4.5: Prescription Drug Market With Multi-Product Firms (Period 1)

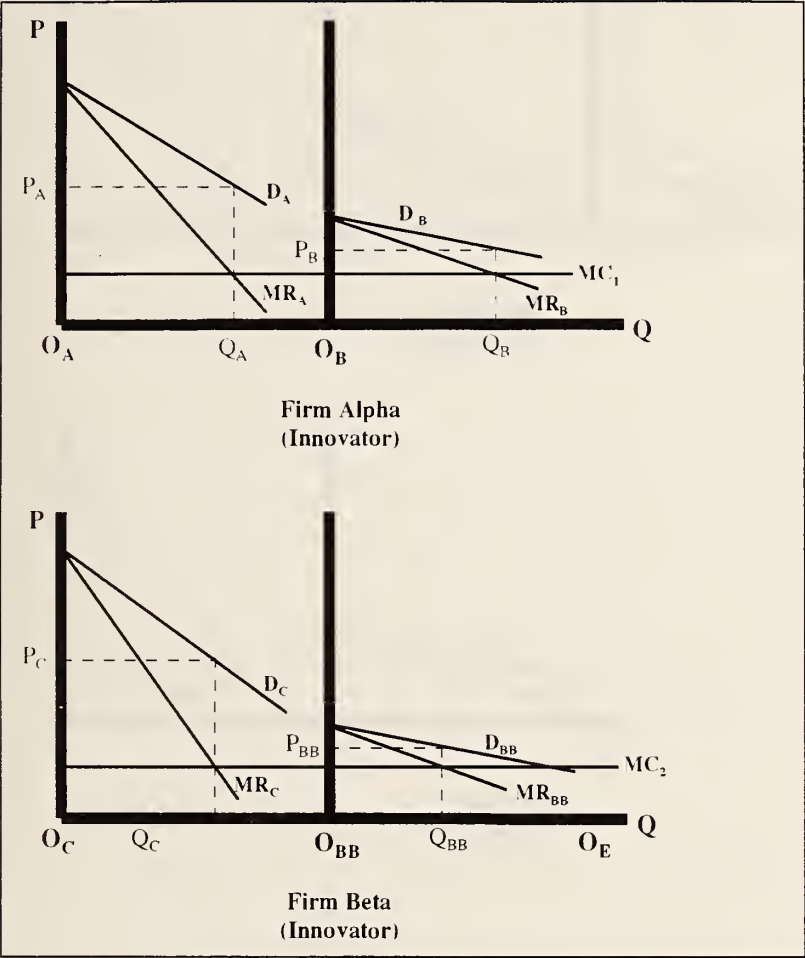


Figure 4.6: Introduction of Competing Drug CC (Period 2)

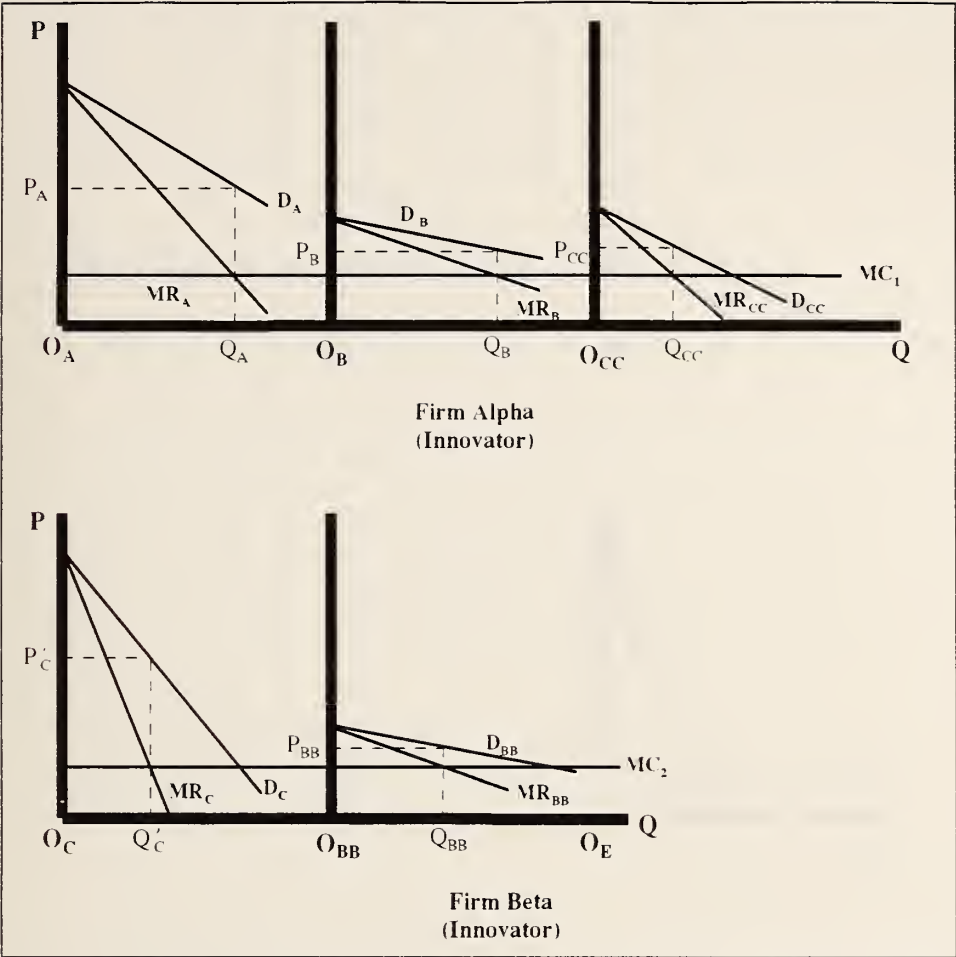


Figure 4.7: Introduction of New Drug by Firm 2 (Period 3)

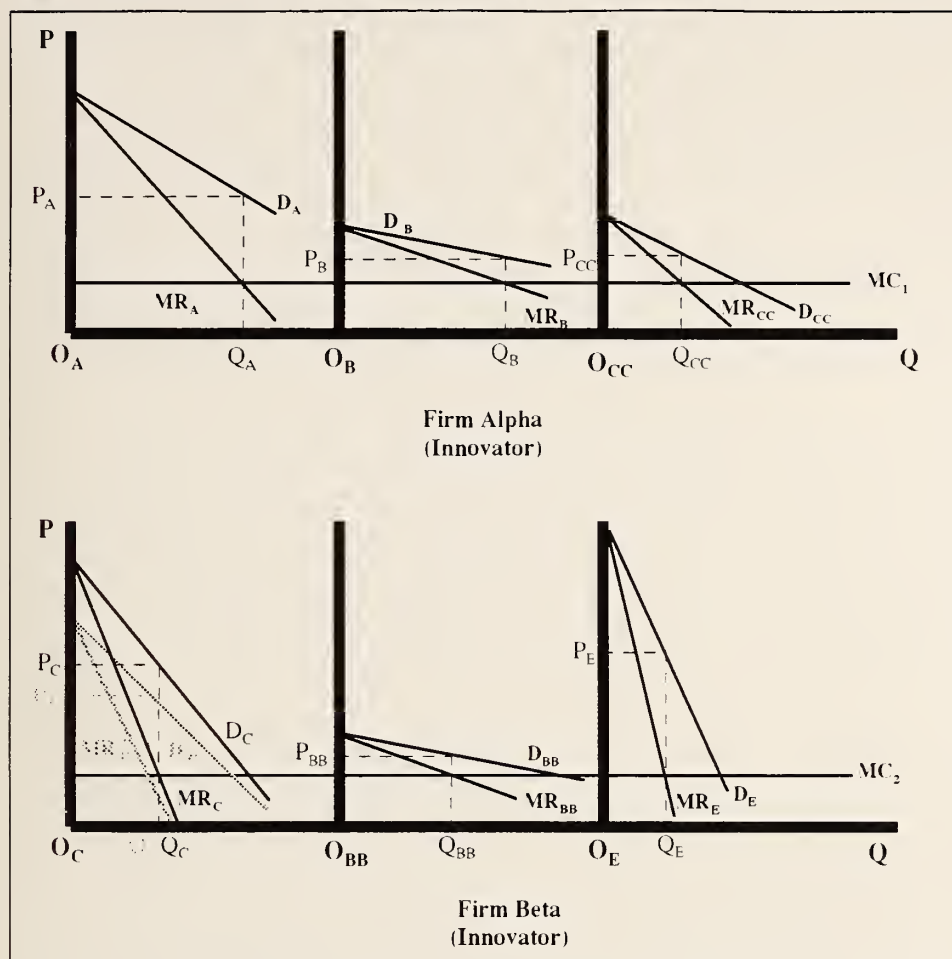
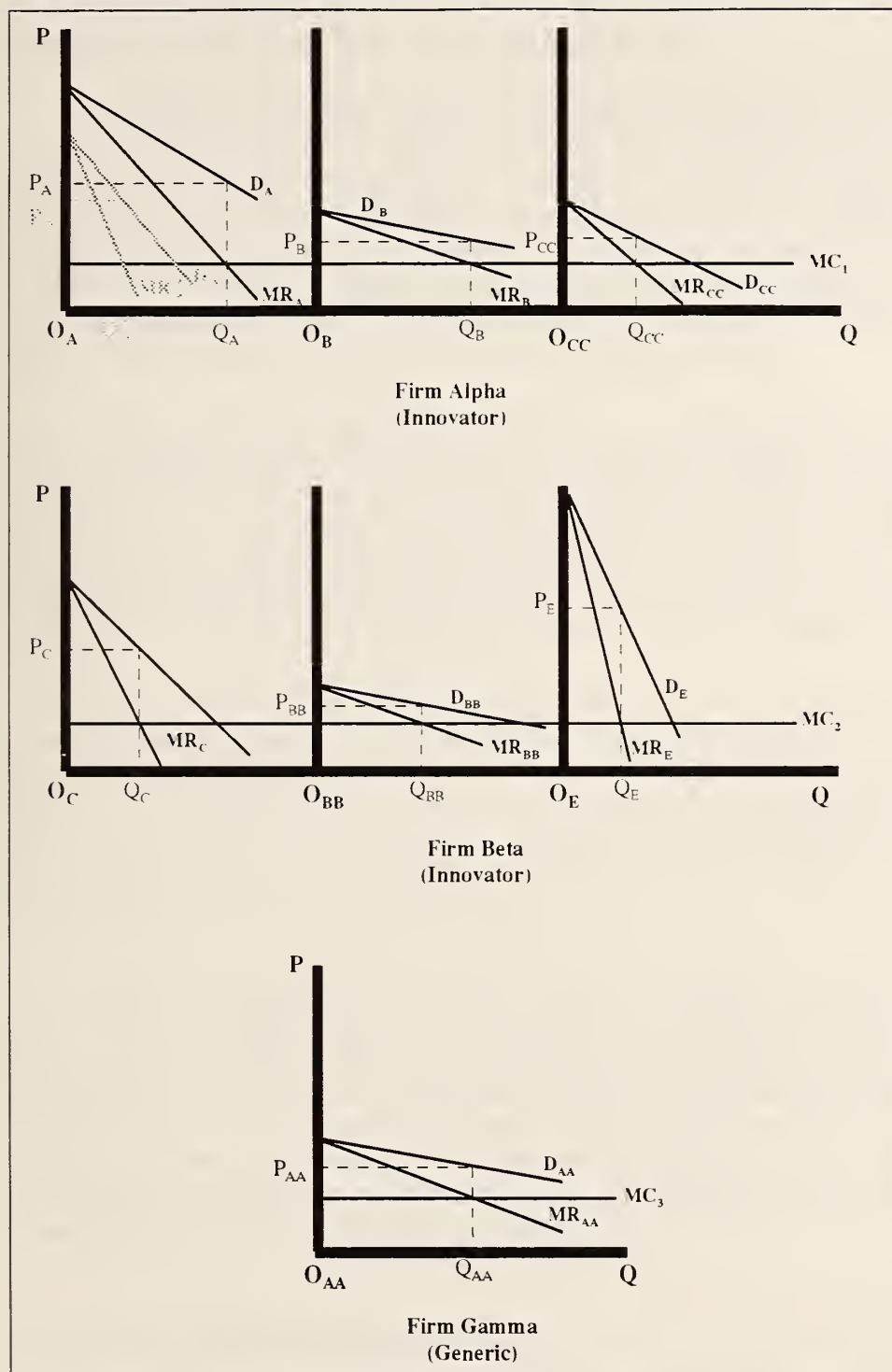


Figure 4.8: Introduction of Generic Substitute of Product A (Period 4)



Application Of The Model To Generic Drug Manufacturers

The nature of the generic drug market suggests a market that is more competitive than the market for innovative products. Manufacturers of generic drugs lack the ability available to manufacturers of originator drugs to use quality differences to differentiate their products from their competitors. By definition, generic substitutes of a single product are bioequivalent to one another. The only way for generic manufacturers to compete is on the basis of completeness of product line or on customer service (e.g. ability to fill orders quickly). As a result, generic drugs tend to compete much more on price than on other qualities--almost like a perfectly competitive market.

Indeed, the price of generic drugs tends to depend largely on the number of generic competitors that are on the market. A number of studies document the drop in generic prices after the entrant of the second, third, and subsequent generic products. Grabowski and Vernon (1993), for example, observed prices for 18 major drug products that lost patent protection between 1983 and 1987. They found that the generic drug price averaged 46 percent of the industry leader one year after the first generic entered the market, and 37 percent one year later, after more products have entered the market.

In the context of the model described above, it will be assumed that the first generic entrant in a market can set price like a monopolist, because that manufacturer is the only "discount" seller in the market (originator drugs tend not to compete against generics on the basis of price). However, the price tends much more towards perfect competition--with zero economic profits--as other firms enter the market. Prices will fall more rapidly the greater the incentives for other firms to enter the market (e.g., the greater the potential market share for generic drugs).

Unlike manufacturers of innovative drugs, it is assumed that generic firms have a cost structure that allow them to charge a lower price while covering long-term average costs. This assumption reflects several differences between generic and innovative drug manufacturers. One of the most significant differences is in manufacturing costs: generic manufacturers do not engage in the lengthy drug development process that drives the operation of innovative firms. In addition, the advertising and marketing expenses of generic firms--particularly in establishing product differentiation--are much lower than are experienced in the innovative segment of the industry.

Model of the Demand for Prescription Drugs

The framework presented in the preceding section carries with it an implicit assumption that the demand for prescription drugs can be represented by a single demand curve. However, given the distinctions in how different segments of the pharmaceutical market that were described previously, the demand is decomposed into several sub-

markets. In order to make our model manageable, we will limit our analysis to four different types of consumers.

Cash-paying, consumers who lack outpatient prescription drug coverage. Over one-third of the over-45 population lacked any kind of prescription drug coverage in 1991, according to one survey,²³ and almost half (46 percent) of the elderly Medicare population lack drug coverage.²⁴ These consumers are assumed to have limited knowledge about the relative prices of branded drugs. They may be aware of differences between generics and brand name drug prices. They are assumed to be price sensitive with respect to the decision of whether to buy drugs or not and, potentially, between generic and brand name drugs, but not between non-generic therapeutic substitutes.

Cash-paying consumers who have some form of outpatient prescription drug coverage. This category includes people who have insurance that pays part of all of the costs paid at the pharmacy. Like their uninsured counterparts, these consumers are assumed to have little or no knowledge about the relative prices of drugs. In addition, because insurance pays a large share of their drug costs, they are less sensitive to price than the uninsured, and therefore will be less likely to substitute generic drugs for brand name counterparts or to inquire with their physician about less expensive brand name drugs.

Institutional buyers. For some consumers, decisions about what drugs are prescribed are heavily influenced by an institution that is involved in the delivery of financing of health care. For outpatient drugs, these institutions include HMOs and purchases made by insured consumers that are managed by PBMs. For inpatient drugs, they include hospitals, nursing homes, or other facilities that affect the decision for drugs. (While there are significant differences in the ability of HMOs, PBMs, and hospitals to influence the demand for prescription drugs, for ease of exposition they are put here as a single group of consumers.) Since these buyers are able to control the distribution network, they are assumed to be able to encourage physicians and consumers to use less expensive products when they are available. This has the effect of increasing the elasticity of demand for products where substitutes exist.

Government buyer. It is assumed that the government is the third-party payer for some segment of the population. This segment may be the poor, the elderly, or a much larger share of the population. Depending on how it sets up its purchasing arrangements, the government may have the same type of demand as either the cash-paying or institutional sectors. Alternatively, it may institute regulations on prices it will pay. For example, the government may require manufacturers to pay the government a rebate between the average price charged to consumers and the

²³ Chilton Research Services, *A Survey on the Need for a Prescription Drug Benefit Under the Medicare Program*. (Report prepared for the American Association of Retired Persons, June 1992).

²⁴ Long (1994)

lowest price that it charges to any customer. For the purposes of this discussion, it is assumed that the government buys drugs in the same way as a non-managed insurer. This assumption will be changed later in the analysis.²⁵

Furthermore, it is assumed that drug manufacturers are able to segment these markets, thereby charging different prices to different market segments. The existence of competitive forces will reduce the prices charged to the price sensitive portion of the market (i.e., the institutional share), and maintain or increase the prices charged to price insensitive portion (e.g., those without adequate information or incentive to switch to more competitively priced products). As Berndt (1994) notes, the pharmaceutical market is characterized by three factors that allow drug manufacturers to segment the market:

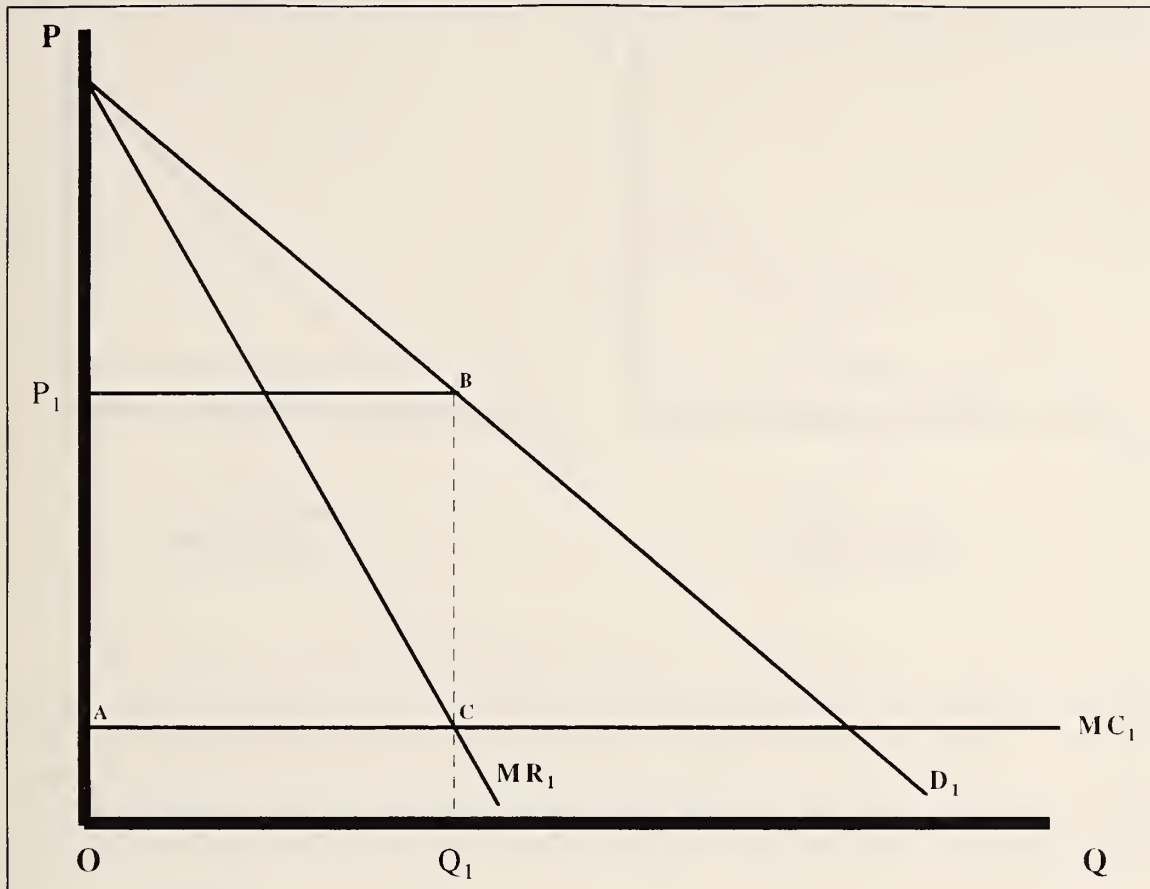
- Possibilities for resale are limited. For example, hospitals are prohibited from selling drugs purchased for inpatient use in an outpatient setting.
- Sellers have some influence over price. This would occur when products are not perfectly homogenous, and producers can differentiate their products on the basis of actual or perceived quality.
- Sellers can segment the buyers according to their different demands for the product. As was shown in the discussion above, this ability exists in the pharmaceutical industry.

A number of studies have documented the trend by which brand name manufacturers segment the market by charging higher prices to segments of the market that are less price sensitive (Caves, et al., 1991; Grabowski and Vernon, 1990; Schondelmeyer, 1994).

Figures 4.9 and 4.10 present a series of graphical presentations of the segmented demand for a single product. In the market described in Figure 4.9, it is assumed that the product is at a stage in its life cycle where there are few, if any, therapeutic substitutes. This lack of substitutability implies that price sensitive buyers (HMOs, hospitals, nursing homes, and pharmacy benefits managers) have little opportunity to negotiate price discounts, and, in effect, have a demand that is not differentiable from the rest of the market. The aggregate demand for the product is shown as D_1 , and marginal revenue is shown as MR_1 . The profit maximizing price will be P_1 , and the profit maximizing quantity will be Q_1 .

²⁵ The federal government is also a direct purchaser of prescription drug, buying some products directly for use in VA and DoD programs. In 1993, this amounted to about \$190 million in sales, or less than one percent of total prescription drug expenditures.

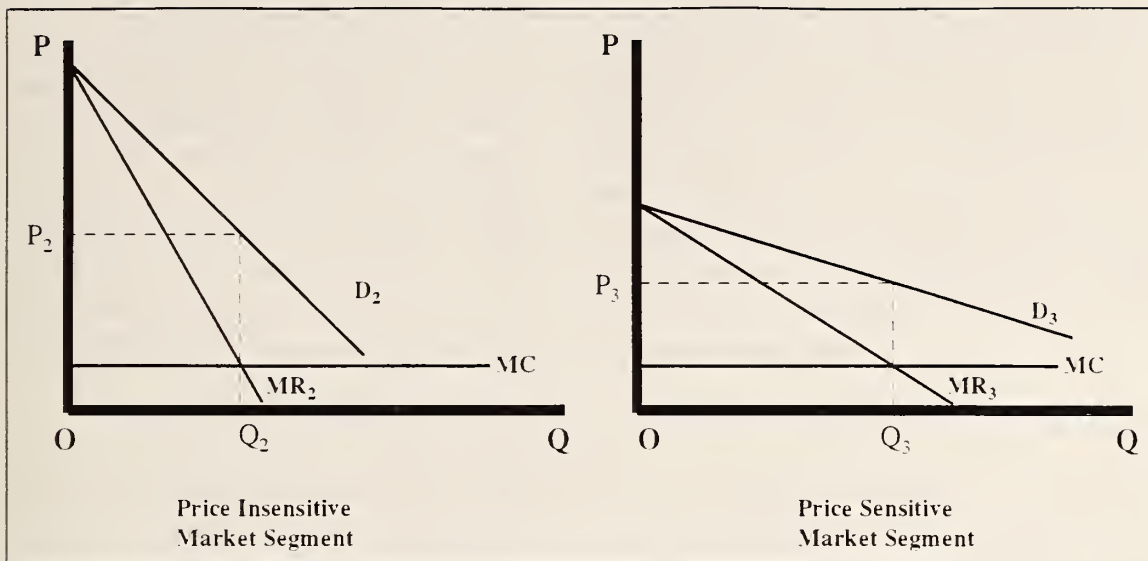
Figure 4.9: Demand for a Prescription



However, as therapeutic substitutes emerge on the market, buyers in the price sensitive share will either buy lower priced generic drugs when they exist, or threaten to buy lower priced brand-name therapeutic substitutes unless this manufacturer agrees to offer price discounts or rebates. By contrast, the price insensitive group is composed of people who are less likely to purchase or be aware of the existence of generic drugs, are not aware of the existence of therapeutically similar drugs, or may be indifferent to drug price because of the structure of their third party pharmacy benefit.

The profit maximizing manufacturer may find it profitable to provide discounts to the price sensitive portion of the market, while maintaining higher prices to the price insensitive portion. In Figure 4.10, the price sensitive portion of the market is represented in the panel on the left, while the price insensitive portion is shown by the panel on the right. The demand curve for the price sensitive portion of the market, D_2 , has both a flatter slope and a lower intercept than D_3 , representing a greater price sensitivity and a lower market share. If the manufacturer sets price as a price discriminating monopolist, then the equilibrium prices will be P_2 for the price sensitive market and P_3 for the price insensitive market.

Figure 4.10: Segmented Demand for a Prescription Drug



The degree of market segmentation is likely to depend on the degree to which manufacturers' monopoly power varies between market segments. For example, when a drug has several therapeutic substitutes, institutional buyers are more able to use their market leverage to force the price competition that does not occur in the retail class of trade. By contrast, when a product has few competitors, institutional buyers have little leverage with which to negotiate price. In this latter situation, there will be little or no market segmentation.

In addition, the slope of the aggregate demand curve relative to the demand for each market segment will depend on the size of each segment and the amount of market leverage that can be obtained by the price sensitive market share. When large share of the market is not price sensitive, then the slope of aggregate demand curve will be relatively close to that of the price insensitive market. But for products where a large share of the market can get discounts, the aggregate demand curve will be relatively flat.

Model of the Pharmaceutical Distribution System

The distribution network for prescription drugs, especially at the outpatient level, has become increasingly complex over the last several years. The traditional relationship entailed manufacturers selling products to drug wholesalers, and wholesalers selling products to the independent and community pharmacies where patients would get their prescriptions filled. With larger pharmacies, manufacturers sold products directly to the retailer, which can efficiently operate its own wholesale operations. In this traditional relationship, pharmacists set prices based on local market conditions. A patient would fill his or her prescription at the pharmacy, and payment would be made either out of pocket or, if the patient had a prescription drug benefit, by the third party payer who provides a reimbursement to the pharmacy.

In recent years, the retail pharmacist has been subject to increasing competition from many sources. First, there has been a broadening of the distribution networks for prescription drugs. Part of this increase is due to the increasing role of grocery stores and mass merchandisers in pharmacy, which, in 1994, filled 19 percent of retail prescriptions. In addition, the role of mail order pharmacies have increased over the years. Mail-order pharmacies, which can be a cost-effective means of filling prescriptions for patients who use drugs for treatment of chronic conditions, accounted for about 9 percent of outpatient prescription drug sales in 1994. Finally, some managed care organizations operate their own pharmacies, offering members an alternative to retail pharmacies. In 1994, this sector accounted for about 4 percent of outpatient prescription drug sales.²⁶

Several factors are assumed to affect the returns to retail pharmacies, including the size of pharmacy fees, the volume of sales, how quickly payments are received, and the amount of competition from other retailers or other distribution networks. For example, increases in third party coverage and the accompanying proactive management of pharmacy costs affect drug retailers in two ways. First, managed care organizations and pharmacy benefits managers generally establish networks in which they limit the fees that pharmacists can charge.²⁷ While some or all of the effect may be negated to the extent that the agreement brings more customers to the pharmacy, the conventional wisdom is that the decreases in pharmacy fees have outweighed any increase in volume. Second, mail order pharmacies and managed care pharmacies may be able to provide better prices to consumers because they are able to get manufacturer discounts that are not provided to retail pharmacies. The impact of these factors is likely to be greater on independent and community pharmacies, which draw a much greater share of their revenues from prescription drug sales than do grocery chains and discount stores.

In addition, increased third party coverage also affects the cash flow of retail pharmacies to the degree to which consumers do not make initial out-of-pocket payments. When third party drug coverage was lower, retailers received most of their payments upon sale. However, with the increase in third-party payment--and agreements for third-party payers to pay the pharmacist rather than requiring the consumer to make a cash outlay--the pharmacist must wait to receive payment. This payment process slows the cash flow for the pharmacist. As with the factors mentioned above, these factors are likely to have a more significant impact on retailers for whom prescription drugs are a greater share of total store revenues.

²⁶National Association of Chain Drug Stores, *Overview U.S. Chain Drug Store Industry 1994*, Nov. 1994.

²⁷The impact of reduced markups may be felt most widely in the sales of generic drugs. While wholesale prices of generic drugs are typically 50 percent or more below the originator price, retail generic prices are often somewhat closer to the branded price, implying that the pharmacist captures some of the price difference. However, when a pharmacy benefits manager sets reimbursement price, it bases its payment on what the retailer actually paid for the drug, plus a fixed reimbursement fee. As the share of sales administered by PBMs rises, the ability of retailers to capture some of the difference between branded and generic prices is reduced.

Model of Pharmaceutical Manufacturer R&D Decisions

Inherent in this dynamic model is the decision by drug manufacturers to enter new markets that they find profitable. As was noted in the earlier discussion, the value of any drug company's product portfolio is limited by the substantial loss in revenues that will occur as the product incurs competition from generic competitors. Entry by brand name competitors can eat into market share and price as well. Not only is the continued development of new products vital to a company's survival as a research-based drug manufacturer, but a substantial revenue stream is needed to support the many years of research, development, and clinical testing required to bring a new product to market. Added to this is the fact that drug development is an uncertain process, and that a firm can expect that it will also be funding research efforts that can result in a "dry well"--that is, efforts that will not result in a marketable product.

In some cases, these profitable areas will be for new product lines for which few, if any, drug substitutes exist. The nature of the pharmaceutical industry suggests that firms must have some of these products in their portfolio in order to continue financing R&D. Other profitable areas can be found in product lines that are well established, although the profits provided by these products might not be as great as the pioneer products. From a policy perspective, there is value in having drug manufacturers produce both new and imitative drugs. Drugs that provide new treatments should be encouraged because they offer a less expensive way to save lives, reduce illnesses, or improve quality of life for patients. To the extent that new products compete on price with existing drugs, the production of imitative products offers a vehicle through which price competition can take place. In addition, these "imitative" products can sometimes offer therapeutic advantages over their predecessors (such as fewer side effects or adverse drug interactions). An optimal policy would be one in which the incentives faced by drug manufacturers result in a balance of these products being produced.

It is difficult for a manufacturer to determine during the R&D or clinical testing process whether the product under development will be a pioneer drug or whether it will be similar to something already on the market. Ideally, manufacturers would like all of their efforts to result in drugs that are the first or second in their therapeutic class, because these products can generate the greatest revenue stream in their life cycle. However, a product's lifetime revenue stream may be reduced if, after clinical testing, it proves to be one that provides only moderate improvement over existing therapies. Alternatively, the drug may look like a pioneer drug during development and perform as expected in clinical tests, but may be approved by the FDA after similar products have reached the market. If it is not one of the first products on the market, then it likely will garner a much lower level of revenues than did its competitors.

The following model represents a framework for analyzing the economic factors faced by drug manufacturers and the choices they make about pharmaceutical R&D under different circumstances. This approach incorporates the literature on pharmaceutical R&D to develop a framework for evaluating a firm's choice of R&D levels as well as the choice

among products. Under this framework, it is assumed that firms engage in two different types of R&D activities. The first is for activities that cannot be ascribed to any particular product. Among these activities is research on the fundamental mechanisms of disease or biological processes; broad biological screening; and early pharmacological testing. Given the long period of time before products could achieve a return on this type of R&D investment, it is assumed that drug manufacturers' willingness to finance these broad, untargeted R&D activities is a function of their overall view of the potential size of the pharmaceutical market several years in the future.

The second set of activities involve development of particular products--turning an active compound into a form suitable for human use; performing toxicology and safety testing; and undergoing regulatory reviews, clinical evaluations, and post approval studies. It is assumed that, at some point in the R&D process, drug manufacturers are able to project what type of products would result from ongoing R&D efforts and to make estimates of the potential market value of those products. (While these projections are not assumed to be perfect indicators of what will occur, it is assumed that at this point firms make judgments on the basis of the best information available at that time. The firms are assumed to be able to rank expected product revenues according to the expected market value of the product and the expectation that development will be successful. Firms will pursue those R&D activities for which expected revenues exceed expected costs.

A simplification of a drug manufacturer's decision making process is where firms can produce three types of products. The first type of product--those that offer important therapeutic gains over existing products--have potentially high revenues but a high risk of ever reaching the market (due to uncertainties about the progress of both drug development, clinical testing, and FDA approval) or of reaching the market before similar drugs produced by competing firms. The second category of products are those which offer little or no therapeutic gain over existing drugs. Because these products are similar to existing drugs, these products can be produced at a relatively low cost and low risk. However, because these products would enter an established market with several competitors, the market opportunities for these new drugs is assumed to be lower. The third category is an intermediate category--drugs that offer modest therapeutic improvements over existing therapies. These drugs may have more risk in development than do drugs that offer marginal improvements, but could potentially offer a greater financial return. A matrix of these factors is shown in Table 4.1.

Table 4.1: Relative Returns of Different Types of Drugs in Development

	PRODUCT TYPE		
	Substantial Improvement	Moderate Improvement	Marginal Improvement
Probability of Drug Reaching Market	Low	Medium	High
Revenue Stream if Drug Reaches Market	High	Medium	Low

For each drug under development, the firm is assumed to be able to calculate expected revenues as the product of the probability of the drug ever reaching the market and the revenues that would be expected if the drug reached the market. This will be compared to the expected cost of continuing drug production to the point of marketing.

As an example, suppose that Firm X has five drugs in development. One of these would represent substantial improvements, two are forecast as moderate improvements, and the others marginal improvements. Table 4.2 ranks these products in terms of their potential market size. In this example, the drug offering substantial improvements offers the largest potential revenues, followed by drugs that offer moderate therapeutic improvements. But when the probability of success is accounted for, this hypothetical firm finds that its most profitable drugs--according to reasonable expectations of its revenues--are those offering moderate improvements.

Table 4.2: Expected Revenue Stream of Drugs in Development for a Hypothetical Manufacturer

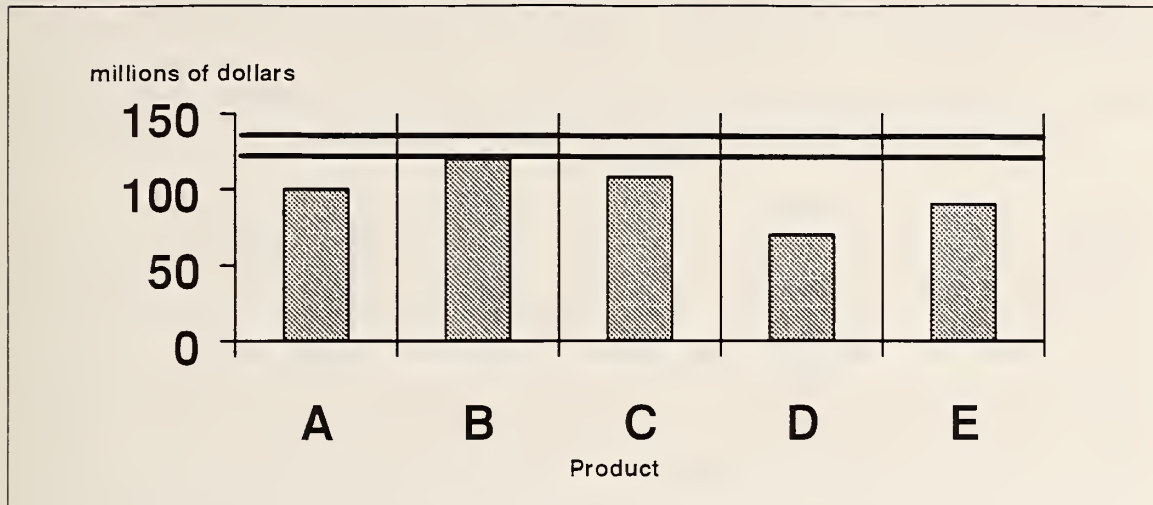
Product	Type of Therapeutic Improvement	Potential Market(\$m)	Probability of Success	Expected Revenues (NPV)
A	Substantial	10,000	0.01	100
B	Moderate	2,000	0.06	120
C	Moderate	1,800	0.06	108
D	Marginal	1,000	0.07	70
E	Marginal	750	0.12	90

The firm is assumed to proceed with developing all drugs for which the net present value of expected revenues exceeds the net present value of expected costs. If the net present value of the additional costs of drug development and clinical testing are assumed to be \$80 million for each product, then the firm will proceed with research efforts on products A, B, C, and E.²⁸ If the costs rise to \$100 million per drug (due, perhaps, to

²⁸ For the purpose of this discussion, development costs are assumed to be the same for all products.

increases in the cost of capital), then only products A, B, and C will continue in the R&D process. (See Figure 4.11)

Figure 4.11: R&D Decisions of the Manufacturer



The expected revenue and cost streams can be affected by the external factors which, as described above, affect the levels of pharmaceutical R&D. In the example given above, these affected the costs stream for all drugs equally. An increase in the cost of capital, for instance, could lead to a uniform increase in R&D costs. However, other changes could affect the cost or revenue stream differently for different types of products. For example, in markets where the reimbursement system leads similar products to compete on price rather than on perceptions of differences in quality, the expected returns on marginal improvements would fall. This would lead to a greater ranking of products with substantial and moderate therapeutic improvements, and would give manufacturers more incentives to develop such products. Several countries' policies are leading toward this type of incentive. For example, the increased use of managed care in the United States makes physicians much more sensitive to drug prices of similar products and makes it more difficult to achieve profitability with new "me-too" drugs. The reference price system, introduced in the late 1980s in Germany, the Netherlands, and Sweden, sets insurance reimbursement rates at levels corresponding a median or average price of all products in a therapeutic category. This has forced manufacturers to set product prices close to the price of competitors (including generic competitors) or lose significant amounts of market share. In the United Kingdom's National Health Service, physicians receive spending targets for drugs and are subject to review if spending significantly exceeds the target. In terms of Figure 4.11, this policy might lead to lower expected revenues for products D and E and possibly for products B and C. Depending on the magnitude of the expected decrease in the potential market size, this could change manufacturers decisions about the whether to produce these products.

By contrast, regulation of introductory drug prices--especially for drugs offering substantial therapeutic improvements--would be expected to lead to a decrease in development efforts for those products. Firms are willing to accept the higher risk associated with developing these products because they offer the hope of a higher return. but regulations that would limit those returns would reduce the risk-reward ratio, and therefore slow the development of new products. These controls would most likely affect products that faced few therapeutic substitutes, such as product A in Figure 4.11. As in the example presented above, binding controls may reduce the expected revenues to such an extent that firms decide it is not worthwhile to proceed with product development.

The preceding discussion relates the direction of impacts, but not their magnitude. Clearly, the magnitude depends on the scope of the change in the market. Detailed information on the scope of each product would be required to evaluate the magnitude of the impacts of such changes on pharmaceutical R&D. For example, in a simulation of the impacts of market changes on new drug innovation, Grabowski and Vernon (1984) estimated that low levels of generic penetration (a 10 percent market share) had little impact on the introduction of new chemical entities (NCEs), but that 50 percent generic penetration after patent expiration results in a 30 percent reduction in the rate of NCE penetration and net revenues from NCE. By contrast, a one year reduction in the length of the FDA regulatory process by 1 year (from 11 to 10 years) results in more than a 15 percent increase in NCE introduction. A two year reduction (from 11 to 9 years) results in about a 25% increase--offsetting the impact of a 50 percent generic substitution with an 8 year patent life.

CHAPTER 5

IMPACT OF PRICING REGULATIONS ON THE PHARMACEUTICAL MARKET

Introduction

The expansion of prescription drug benefits--whether for the general population or for certain groups (such as the Medicare population)--reduces the financial barriers that can prevent people from receiving drugs needed for appropriate medical treatment. Prescription drug benefits, such as those proposed in the 1994 Health Security Act and those in place in several other industrialized countries, expand access by reducing the effective price of prescription drugs to consumers. However, by shielding the consumer from the cost of the drug, the program also removes the financial incentives that promote use of the least cost or most cost effective drug, reduce unnecessary utilization, and promote competition and efficiency in the pharmaceutical market. As a result of these market imperfections, public and private third-party payers have established a variety of policies intended to reduce the cost of a prescription drug program and promote more cost effective use of prescription drugs. The next two chapters present an analysis of the impacts of those approaches.

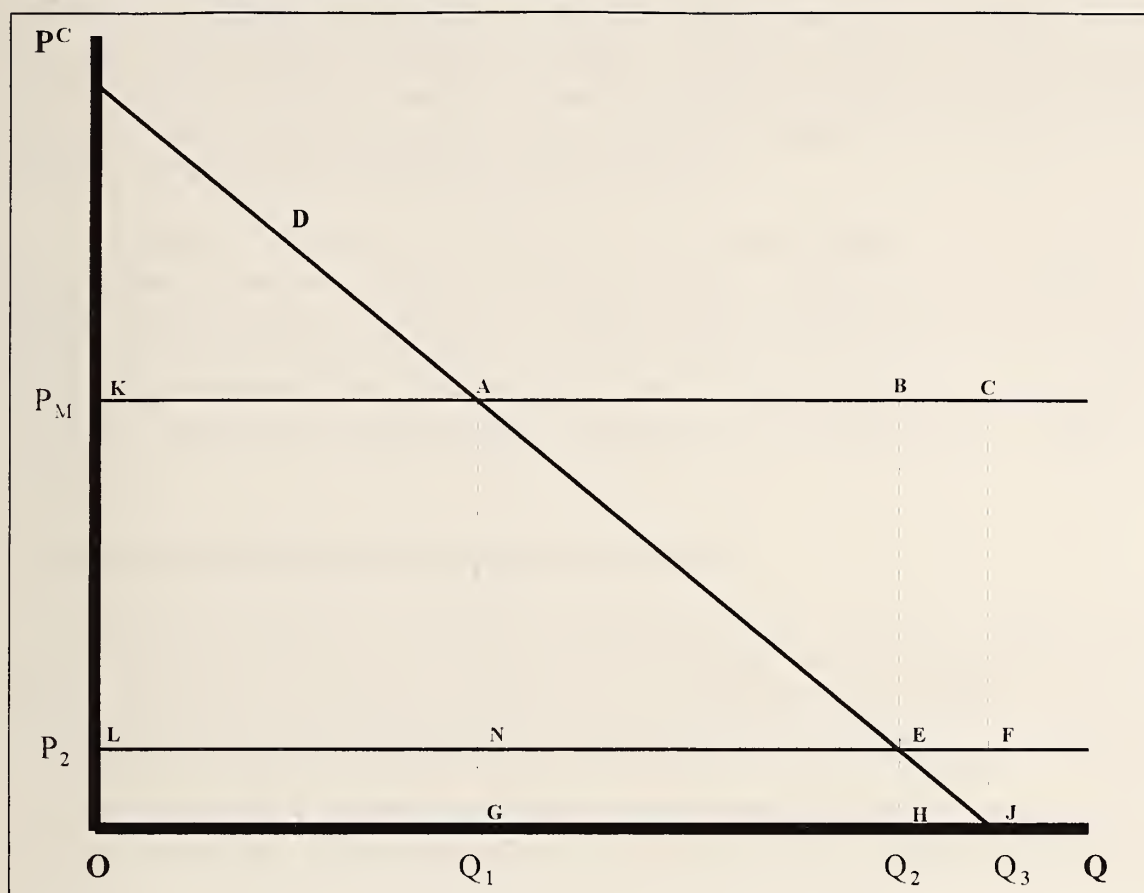
Impacts Of Expanding Insurance Coverage

Prescription drug benefits expand access to prescription drugs by reducing the effective price of drugs to consumers. While this expansion reduces the likelihood that drug cost will be a barrier to necessary care, the lower price also creates incentives for inefficient and unnecessary consumption by consumers. This pattern, which economists refer to as *moral hazard*, results in increased drug utilization (possibly beyond that necessary for appropriate treatment), higher costs, reduced incentives for seeking lower cost treatments, and increased welfare loss. The more generous an insurance benefit, the greater are the impacts of moral hazard.

An illustration of the impact of drug insurance coverage is illustrated in Figure 5.1.¹ Figure 5.1 shows the demand for prescription drugs by a typical individual. The horizontal axis measures the price paid by the consumer, which is denoted as P^C . The demand curve is drawn so that the consumer responds to P^C rather than to market price, P . For example, for the demand curve labeled DJ in Figure 5.1, the market price is fixed at P_M . While quantity demanded will vary with differences in P_M if the consumer has no insurance coverage, it will also vary with changes in insurance coverage even as the market price remain unchanged. For simplicity, it is assumed that demand is a linear function of price, and that demand is not perfectly inelastic; that is, that quantity demanded increases as price decreases.

¹ This discussion is adapted from McMillan and Jankel (1993).

Figure 5.1: Impact of Insurance Coverage



The illustration also shows how insurance coverage both increases consumer access to drugs and creates inefficiencies in the prescription drug market. Assume that the P_M represents the average market price for drugs in the consumer's market basket. The consumer whose demand is illustrated in Figure 5.1 would purchase quantity Q_1 of prescription drugs. Quantity demanded can increase in one of two ways: by a decrease in the average market basket price, or by an increase in insurance coverage. Suppose that the average price falls to P_2 . This will be accompanied by an increase in quantity demanded to Q_2 . Additional consumer welfare increases by area ANE , with no welfare loss to society. By contrast, suppose that market price remains unchanged at P_M , but that an increase in insurance coverage reduces the effective price to the consumer to P_2 . Total drug costs will increase by area $ABHG$. Of this amount, only the area under the consumer demand curve between Q_1 and Q_2 --area ANE --accrues to the consumer in the form of increased benefits. The remainder, area ABE , represents a social cost to society.

These impacts increase as insurance coverage increases. At the extreme case of 100 percent coverage, the effective cost to the consumer is zero. Quantity demanded rises to Q_3 , and total costs become area $OKCJ$. The increased benefit to the consumer is area AJG , while the excess government cost is area ACJ .

It is also possible that the increased insurance coverage expands drug utilization beyond that which is medically “necessary”. Suppose, for example, that Q_2 represents the level of drug utilization that is needed to maintain good health. If insurance reduces the effective price below P_2 , the consumer will have an incentive to purchase a greater quantity of drugs than are medically necessary.² This means that society would be incurring a welfare loss beyond that needed for people to obtain medically necessary prescription drugs.

Another way that insurance coverage can contribute to inefficient drug expenditures is in affecting the mix between consumption of more and less expensive products that have similar therapeutic effectiveness. Consumers with high insurance coverage are relatively insensitive to differences in prices of similar drugs. They will have little incentive to reduce the average price of their market basket by using less expensive generic drugs or relatively cheaper therapeutic substitutes. This leads to higher program costs and, as in the previous case, inefficient use of resources.

Rationale for evaluating drug reimbursement policies

As noted in Chapter 3, government drug expenditures in excess of consumer willingness to pay can be interpreted as the cost to society of equalizing access to prescription drugs. Under this interpretation, government’s adoption of a prescription drug benefit reflects society’s willingness to accept some financial costs in order to gain the social benefit of increasing access to health care to its members. However, society’s willingness to incur such costs are not unlimited. Publicly funded health programs continually face fiscal pressures to reduce costs, including those for prescription drugs. These programs may be designed to both constrain costs and to increase efficiency.

Our analysis of efforts by the government to declare the social and financial costs of a prescription drug benefit will focus on three sets of approaches:

- The first is to reduce the average market price for drugs. One approach for restricting market prices is to either regulate prices charged in the market (that is, force down P_M for all consumers) or to regulate the prices that can be charged to a government-financed program such as Medicaid or Medicare.
- A second set of policies is aimed at reducing the level of drug utilization. Two particular approaches for reducing utilization are discussed in this report. One is to increase the effective price paid by consumers (that is, reduce the level of insurance

² Since these drugs are available only with a physician’s prescription, the physician plays an important role in determining the quantity demanded. We assume that the physician is influenced by price as well as by appropriate medical practice. For example, if the physician knows that the effective price of a drug is less than that of another drug for another alternative therapy, then she might choose that drug for treatment even though treatments with higher effective prices are equally or more effective. This is not to say that the physician would choose the less effective treatment simply because it is less expensive. Rather, we assume that when the physician is aware of price, she recommends treatment based on what is, in effect, a simple cost-benefit analysis where the cost is the effective price to the consumer.

coverage). Another is to influence the physician who plays a major role in determining what drugs are to be purchased.

- A third approach is to let managed care organizations--such as HMOs or pharmacy benefits managers (PBMs)--administer a prescription drug benefit (and to provide them with incentives for efficient management). These organizations can use approaches applied in the private sector to obtain price discounts from manufacturers and to control utilization.

The analysis will focus on several concerns of the government in developing policies affecting the pharmaceutical market. First, because government is concerned with the cost and cost effectiveness of the prescription drug benefits it provides, the analysis will examine the impact of each approach on program cost and efficiency of the drug benefit program. Second, because government is concerned with the welfare of program beneficiaries, it will examine how policies affect consumer access to existing drugs as well as the development of future products. Third, since the government is concerned with promoting competitive forces in the health care market overall, our analysis will, where appropriate, review how each policy affects competitive forces in the pharmaceutical market, such as the strengthening of the generic drug sector, promoting price competition between products, and affecting the ability of efficient payers to find alternative ways of cost-effectively purchasing pharmaceuticals. Finally, reflecting the role of government in promoting a strong research-based pharmaceutical industry, the analysis will examine how each policy affects overall manufacturer profitability and the incentives for pharmaceutical manufacturers to engage in R&D for innovative drug products.

The remainder of this chapter focuses on how one set of policies--drug pricing regulations--affect these components of the pharmaceutical market. These policies target the prices charged by drug manufacturers because manufacturers' charges account for the largest share--about two-thirds--of total prescription drug costs. Policies that restrain the prices that manufacturers charge--combined with limits on fees that can be charged by pharmacists or other drug distributors--can play a large role in reducing costs to private and public third-party payers as well as to consumers (to the extent that they pay some of the costs of the drugs they use).

The analysis will also examine the unintended and adverse consequences that drug pricing regulations can have on the pharmaceutical market. First, the controls can decrease competition by reducing incentives for competitors to enter markets that, in the absence of price controls, would have been more profitable. This absence of competition can stifle innovation of therapeutic improvements as well as create a welfare loss that comes from regulating prices rather than letting them fall naturally. Furthermore, they have the potential to affect pharmaceutical R&D in two ways: first, decreasing the funds available for pharmaceutical R&D; and second, shifting the incentives for engaging in R&D from major therapeutic improvements to more minor improvements or "me-too" drugs.

The analysis in this chapter applies the model of the pharmaceutical market developed in Chapter 4 to four types of pricing policies:

- *rebates* that manufacturers pay to the government for drugs purchased under a government drug benefit;
- *direct price controls* under which the government sets or negotiates drug prices that will be charged for the entire market;
- *price review boards* that limit launch prices or price increases on a subset of drugs (typically those that have a limited number of therapeutic substitutes); and
- *unitary pricing laws* that restrict the ways in which manufacturers can charge different prices to different market segments.

This analysis is followed in Chapter 6 with an analysis of other government policies aimed at influencing drug utilization choices made by consumers, physicians, and managed care organizations that provide benefits to Medicare or Medicaid beneficiaries.

Manufacturer Rebates

There are several ways that the government can control the prices of prescription drugs. One is to set or negotiate prices and reimbursement rates for all insurers. An alternative, however, is to limit the prices paid only for those programs financed, in whole or in part, by the federal government. The drug manufacturer rebates that are part of the Medicaid program and that were included in last year's proposed Medicare drug benefit are one example of this latter approach. These policies are designed to tie prices paid by federally funded drug programs to the lowest prices charged by drug manufacturers to any of their private sector customers. As designed for the Medicaid and Medicare programs, drugs are sold to program beneficiaries at market prices. However, each drug manufacturer pays a rebate to the government based on the amount of sales it makes to the public program and the lowest prices that it charges for each drug to its private customers.

Manufacturer rebates have, since 1990, been a key element of Medicaid drug payment policy and were included in the Medicare drug benefits proposed during the recent health reform debate. The premise for instituting a drug rebate in a publicly funded prescription drug benefit is a perception by government that, as the highest volume purchaser of prescription drugs, it should not pay prices that exceed those charged to other purchasers.³ Drug manufacturers can, under certain conditions, maximize profits through price discrimination; that is, charging different prices to different "classes of trade".⁴ The retail class of trade, where most Medicaid and Medicare beneficiaries fill their prescriptions,⁵ usually has to pay a higher price than other sectors because it

³ U.S. Senate (1990). The Medicaid program itself is the highest volume purchaser of prescription drugs. Adoption of a Medicare drug benefit would significantly increase this role, since the elderly have the highest levels of drug utilization. The 65-and-older population, most of whom would be covered under a Medicare drug benefit, currently account for an estimated one-third of prescription drug costs (CBO, 1994, p. 22).

⁴ See, also, Png (1991) and Mullins (1995).

⁵ According to HCFA data, about 23 percent of Medicaid and 9 percent of Medicare recipients were enrolled in managed care plans in 1994.

has little or no leverage with which to negotiate price discounts with manufacturers. Retail pharmacies typically must stock a wide range of products in order to meet customer needs. They lack the power to shift consumer utilization, and cannot stop buying from manufacturers who do not give discounts. By contrast, other classes of trade--such as HMOs, hospitals, and mail order houses--can negotiate price discounts with manufacturers because they can opt not to buy products that have therapeutic substitutes, or, alternatively, can offer to increase market share of products for which discounts are given. Since prices charged by drug manufacturers are the largest component of prescription drug costs (accounting for over two-thirds of average retail price⁶), discounts from the manufacturer price can significantly affect prices paid by Medicaid and Medicare beneficiaries.

Medicare beneficiaries and--prior to the 1990 imposition of the Medicaid rebate law--state Medicaid programs typically paid the prices that are charged to the retail class of trade. This pricing reflects the fact that Medicaid and Medicare beneficiaries typically fill their outpatient prescriptions at retail pharmacies. The stock from which the pharmacist fills these prescriptions is indistinguishable from other stock. Therefore, so long as retail pharmacies do not obtain discounts given to other classes of trade, then the manufacturer charge to Medicaid and to Medicare beneficiaries reflects the higher price charged to the retail class of trade⁷.

Imposition of a rebate does not change the way that beneficiaries obtain their prescriptions, nor does it directly affect the prices charged by manufacturers for drugs sold to these beneficiaries. Rather, it is a chargeback applied *ex post* to the manufacturer, based on data on beneficiary drug purchases of individual products and on best price for each product (data on which must be provided by the drug manufacturer). For the Medicaid program, for example, the rebate amount equals the greater of (1) a fixed percentage (12.5 percent in 1991 and 1992; 15 percent after 1992) of the average manufacturer price (AMP)⁸ or, (2) the difference between the AMP and the lowest, or "best", price any purchaser paid for the drug. The rebate for generic drugs is similarly calculated, except that the applicable rate is 11 percent. In addition, if the AMP on non-generic drugs rises faster than the general price level (as measured by the CPI-u), then the rebate also includes an additional inflation adjustment. There is no inflation adjustment for generic drug products (Schondelmeyer, et al., 1995). The rebate amount is computed by the Department of Health and Human Services, based on the best price and AMP data that the manufacturers provide each quarter, and drug utilization information that is provided by state Medicaid programs. Rebates are paid by drug manufacturers to state Medicaid programs (GAO, 1994b). If the manufacturer's best price on a product is less than 15 percent below the AMP, then the per unit rebate is equal to 15 percent of the product's AMP.⁹ However, if the best price

6 Drake, Donald and Uhlman, Marian, *Making Medicine, Making Money* (Kansas City, Mo.: Andrews and McMeel), 1993 cite a study by Stephen Schondelmeyer in which he found that manufacturer prices account for 69 percent of the price of prescription drugs.

⁷ By contrast, the dispensing fee and product markup charged by the pharmacist may differ between Medicaid and non-Medicaid customers. State Medicaid programs set their own policies (subject to federal standards) for these components of the Medicaid drug charge (see Adams, Kreling, and Gondek, 1994).

⁸ The AMP is the average price paid to a manufacturer by retail pharmacies or wholesalers for drugs distributed to the retail pharmacy class of trade.

⁹ For generic drugs, the rebate amount is 11 percent of AMP or the difference between AMP and best price.

is 15 percent or more below the AMP, then the per unit manufacturer rebate is equal to the difference between the AMP and the best price.

The Medicare rebate proposed as part of the Clinton Administration's Health Security Act differed slightly from the Medicaid rebate. The proposed Medicare drug rebate would be the greater of: (1) 17 percent of the average manufacturer retail price (AMRP)--the average price paid to manufacturers for drugs sold by pharmacies and other retailers--or (2) the difference between the AMRP and the average manufacturer nonretail price--the average price paid by institutional purchasers (including the Department of Defense and the Department of Veterans Affairs). The structure of the rebate ensured that the government price would be less than or equal to the average institutional price.¹⁰ No rebate would be applied on generic drugs (although generic drug rebate was included in the version of the bill passed by the House of Representatives' Ways and Means Committee).

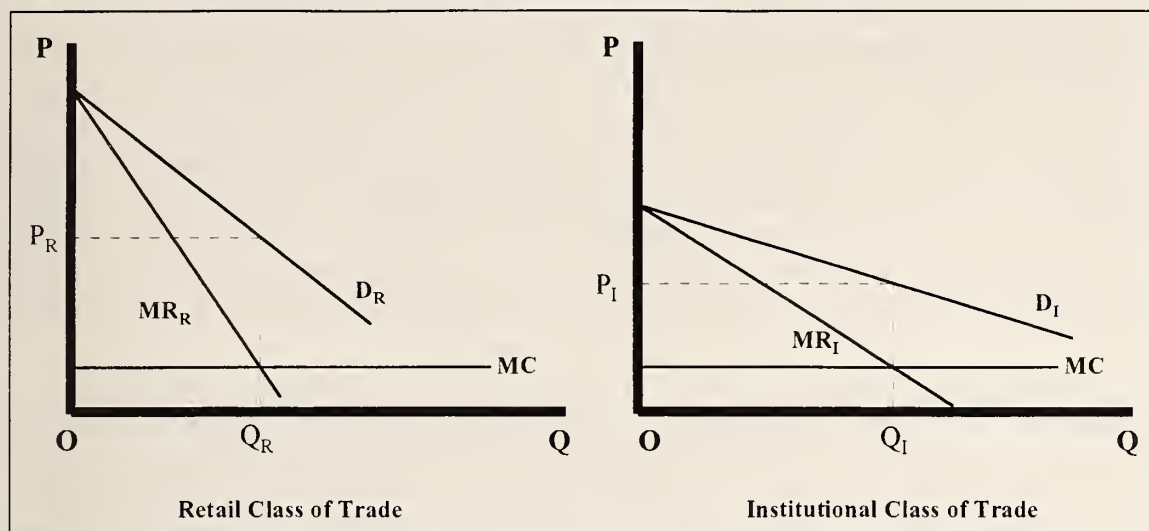
Analysis of the Impacts of a Drug Manufacturer Rebate

The conceptual model of the pharmaceutical industry is used to examine the direct and indirect impacts of the manufacturer rebate on drug benefit costs, on prices charged by manufacturers to different market segments, on returns to drug manufacturers, and on incentives for drug R&D. In order to see the effects of a rebate, we will use as an example the current Medicaid drug rebate. The analysis first focuses on the impacts on a particular product produced by a single firm, using the model to analyze how the rebate initially affects the manufacturer, how the manufacturers' reactions affect other market participants, and how that reaction affects different classes of trade (that is, the retail class of trade and other purchasers). The analysis is then extended to a multi-product context in order to understand how the rebate might affect the production decisions by a single firm. Finally, we discuss the long-run impacts of the rebate on R&D decisions by the firm.

The analysis begins with the impact of the policy on a single firm. We assume that the firm is able to segment its market into two separate classes of trade and, furthermore, that the firm finds such segmentation to be profitable. The retail class of trade, denoted in the left panel of Figure 5.2, is assumed to be a sector in which neither payers nor consumers negotiate price discounts with manufacturers. As such, the demand for the product, D_R , is relatively price inelastic. The institutional class of trade, denoted in the right panel of Figure 5.2, is one in which payers are able to negotiate discounts with manufacturers. These institutions--which include hospitals, nursing homes, HMOs, mail order pharmacies, and payers contracting with PBMs--can obtain discounts because they can effectively threaten to use competing products; the greater the number of therapeutic substitutes, the greater the discount that can be extracted. In Figure 5.2, the demand of the institutional class of trade, D_I , is depicted as being more price elastic than the demand of the retail class of trade. For purposes of simplicity, it is assumed that all payers in the institutional class of trade pay the same price (or, conversely, obtain the same level of discount). It is further assumed that the firm faces constant marginal costs of production (MC in Figure 5.2), and that those marginal costs do not vary by class of trade.

¹⁰ Congressional Budget Office (1994).

Figure 5.2: Segmentation of the Market for a Prescription Drug



For this example, it is assumed that the retail class of trade accounts for sixty percent of the prescription drug sector.¹¹ Medicaid is assumed to be in the retail class of trade prior to the imposition of the rebate. Since Medicaid accounts for about 15 percent of outpatient drug market,¹² Medicaid is assumed to account for about 25 percent of the retail drug sector.

According to the example illustrated by Figure 5.2, manufacturers charged price P_R to the retail class of trade prior to the rebate, and P_I to the institutional class of trade. P_R refers to the component of retail price paid to manufacturers by both retail customers¹³ and state Medicaid programs¹⁴, and is higher than the institutional sector price, P_I . P_I is the ‘best price’ charged by this firm for the drug, and the Average Manufacturer Price, or AMP, is equal to $(P_R Q_R + P_I Q_I) / (Q_R + Q_I)$.

Initial effects of imposing a rebate. The initial impact of the rebate will be to have manufacturers pay to the government a portion of P_R for each unit of the product sold to Medicaid. This payment will reduce the effective price that government will pay for drugs for Medicaid beneficiaries.

¹¹ The retail class of trade includes HMOs that do not have pharmacy benefit management programs in place. Estimates of the share of the population receiving managed pharmacy benefits vary. However, a 1992 analysis showed that the cash paying retail sector accounted for 55 percent of the prescription drug market, and suggested that a significant share of the non-retail sector was not in a managed pharmacy program (GAO, 1994b). Therefore, the assumption that 60 percent of the market pays the prices paid in the retail sector appears to be reasonable.

¹² Levit, et al., (1994).

¹³ By ‘retail customers’, we refer to consumers who buy drugs at retail pharmacies and who are not enrolled in a managed insurance program. While many insurers that manage their pharmacy benefits allow patients to fill prescriptions at a retail pharmacy, these payers do not pay the full retail manufacturer price. Rather, they negotiate discounts or rebates that are paid subsequent to the purchase. For the purposes of this discussion, the terms retail customer or retail sector apply only that segment of retail drug purchases that are not managed.

¹⁴ To the extent that Medicaid beneficiaries are enrolled in managed care programs that have a pharmacy management program in place, some Medicaid purchases would be not be captured by the fee-for service market segment.

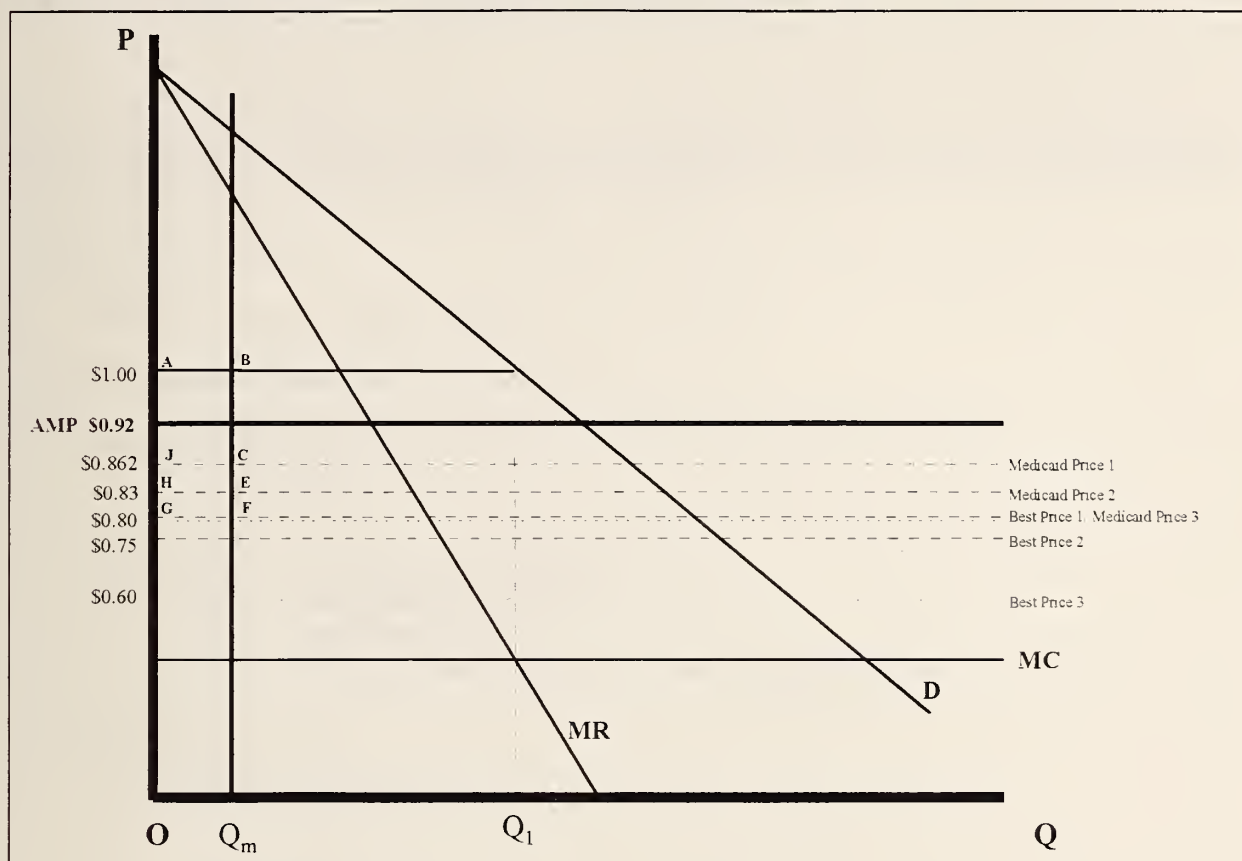
The size of the per unit rebate will depend on the relationship between the best price and the Average Manufacturer Price. For example, suppose that the manufacturer charges \$1.00 per unit to the retail class of trade, and \$0.80 to the institutional class of trade (since all buyers in the institutional class of trade are assumed to receive the same price, \$0.80 is the best price). Assume, furthermore, that the institutional class of trade accounts for 40 percent of the market, so that the AMP is \$0.92. According to the rebate formula, the per unit rebate is the greater of: (1) 15 percent of the AMP, or \$0.138, and (2) the difference between the best price and the AMP, or \$0.12. The rebate is therefore \$0.138, and the effective price paid by the government is \$0.862 per unit. In this case, the Medicaid price is below the average price but above the best price.

The rebate structure means that greater differences between the AMP and the best price reduce the effective price paid by the government. For example, suppose that differences in prices charged to different manufacturers in the institutional sector led to an AMP of \$0.92 but that one particular institutional purchaser was able to negotiate a price of \$0.75 per unit. Then the difference between the AMP and new best price--\$0.17 per unit--would exceed 15 percent of the AMP. The rebate would be \$0.17 per unit, and the effective price paid by Medicaid would be \$0.83 per unit. If the best price had been \$0.60¹⁵, then the rebate would be (AMP-\$0.60), or \$0.32 per unit, and the effective Medicaid price would be \$0.68. (The AMP will not change with the imposition of the rebate, because at this point in the analysis we are assuming that the rebate has not changed the price charged.)

Figure 5.3 illustrates the market for the retail class of trade for the example just described and shows how rebates of different sizes directly affect revenues received by manufacturers. Prior to the imposition of the rebate, the price in this market is determined by the intersection of the marginal revenue and marginal cost curves for each class of trade. Equilibrium price is \$1.00 per unit, and equilibrium quantity is Q_1 . The AMP is shown at \$0.92 per unit, and three different hypothetical best prices, \$0.80, \$0.75, and \$0.60 are shown, as well as the corresponding effective Medicaid prices.

¹⁵ When the best price is this far below the AMP, it implies that a relatively small share of the market is receiving best price.

Figure 5.3: Effect of Medicaid Rebate Under Different Best Price Scenarios



Assume that the Medicaid share of the market is Q_m . At a best price of \$0.80, the effective Medicaid price is \$0.862, and the manufacturer loses revenues of 13.8 cents for every unit sold to Medicaid (assuming that the rebate does not result in any shift in demand). This revenue loss is represented in Figure 5.3 by the area ABJC. If, however, the best price had been \$0.75 (and the corresponding Medicaid price \$0.83), then the revenue loss be the larger area ABEH. If the best price was actually \$0.60, the revenue loss corresponding to the effective Medicaid price of \$0.32 would be area ABGF.

It is interesting to note that the rebate law can result in only small discount when a large share of the market is in the institutional class of trade. In fact, the rebate may be so small that the post rebate price to the government will actually *exceed* the AMP. For example, suppose that the retail price is \$1.00 per unit, and that the institutional class of trade pays \$0.70 per unit. Furthermore, suppose that the institutional class of trade accounts for two-thirds of the outpatient market for this product.¹⁶ Then the AMP is \$0.80 per unit. According to the rebate formula, the rebate is the greater of (1) 15 percent of the AMP, or 12 cents; or (2) the difference between the best price and the AMP, or 10 cents. With a 12 cent per unit rebate, the post-rebate price to the

¹⁶ This market share is not unreasonable. Some analysts suggest that the managed care portion of the pharmaceutical market will reach 85% percent by 1997. See *The Pink Sheet*, February 13, 1995.

government is \$0.88, which exceeds the AMP by 8 cents per unit. This result will occur when the institutional market has at least a 50 percent market share.^{17, 18}

¹⁷ The Medicaid rebate is designed such that the post-rebate Medicaid costs will always exceed when (1) the retail price exceeds the AMP by more than 15 percent, and (2) the AMP when at least one-half of the market receives a discounted price. This is proved by the following set of equations:

First, the rebate is defined as :

$$(1) \quad \text{Rebate} = \rho = \max (.15 * \text{AMP}, \text{AMP} - P_I)$$

The AMP is the average manufacturer price, defined as:

$$(2) \quad \text{AMP} = \frac{P_R Q_R + P_I (1 - Q_R)}{Q_R + (1 - Q_R)}$$

where Q_R = cashing paying market share
 $1 - Q_R$ = institutional market share
 P_R = cash paying price
 P_I = institutional price (assumed to be same for all institutions)

Substituting (2) into (1) yields.

$$\begin{aligned} (3) \quad \rho &= \frac{P_R Q_R + P_I (1 - Q_R) - P_I}{Q_R + (1 - Q_R)} \\ &= \frac{P_R Q_R + P_I - P_I Q_R - P_I}{1} \\ &= Q_R (P_R - P_I) \end{aligned}$$

The post-rebate cost to Medicaid of a drug bought by a Medicaid beneficiary is the difference between the retail price and the rebate, or

$$(4) \quad P_m = P_R - \rho$$

The following set of equations shows the conditions under which the post-rebate Medicaid price would exceed the AMP when the AMP is more than 15 percent below the retail price:

$$\begin{aligned} (5) \quad P_m &> P_R Q_R + P_I (1 - Q_R) \\ P_R - \rho &> P_R Q_R + P_I (1 - Q_R) \\ P_R - Q_R (P_R - P_I) &> P_R Q_R + P_I - P_I Q_R \\ P_R - P_R Q_R + P_I Q_R &> P_R Q_R + P_I - P_I Q_R \\ P_R - P_I &> 2 (P_R Q_R - P_I Q_R) \\ P_R - P_I &> 2 Q_R (P_R - P_I) \end{aligned}$$

or,

$$(6) \quad 1/2 > Q_R$$

Manufacturer reaction to the rebate: cost shifting. According to this analysis, the rebate can be appropriately thought of as a tax on manufacturers that is targeted to the Medicaid prescription drug benefit. Rather than reducing the price outright, it requires the manufacturers to return a share of its revenues to the government. The revenue losses shown in Figure 5.3 are calculated under the assumption that the manufacturer does not try to reduce the cost of the rebate by either (1) reducing the difference between the AMP and the best price, or (2) shifting the costs onto consumers by price increases. Economic theory suggests that manufacturers will adopt both of these approaches in an attempt to reduce the tax. The result of these actions will shift the some of the incidence of the rebate (or tax) from drug manufacturers to payers and consumers in both the retail and the institutional classes of trade.

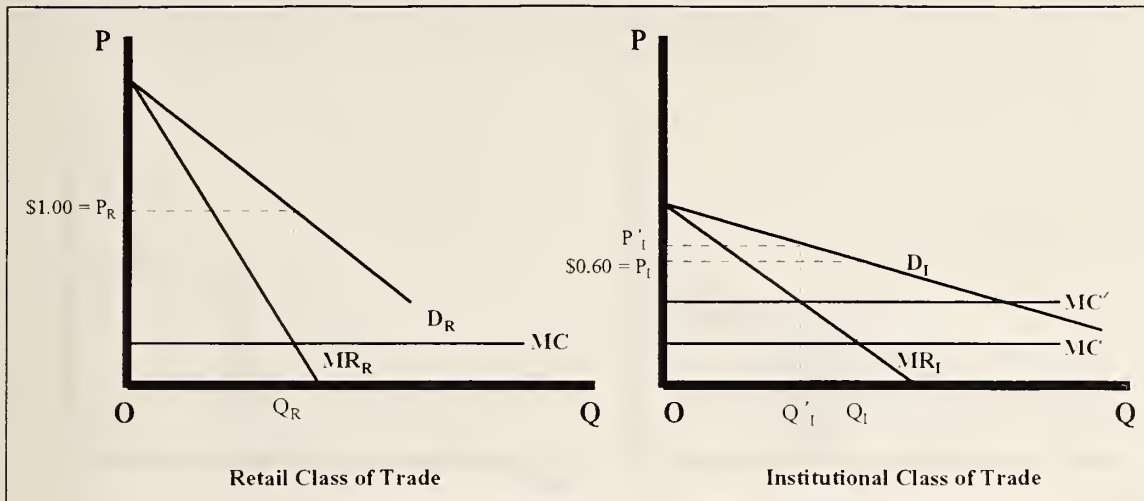
For example, since the “tax payment” increases with the difference between the AMP and the best price, it should be evident from Figure 5.4 that a manufacturer can reduce its revenue loss by increasing the best price. Indeed, it can be shown that increasing the best price is an effective means of reducing the rebate so long as the best price is less than $(1-r)*AMP$, where r is the rebate rate. In economic terms, the rebate increases the cost of selling in the institutional class of trade as long as best price exceeds $(1-r)*AMP$. This is illustrated in Figure 5.4, where the increase in the marginal cost curve (shown as MC') shows the increased costs associated with having to pay a per unit rebate of $(AMP - \text{best price})$.¹⁹ The shift in the marginal cost curve reflects a convergence between the impacts of raising the best price and the resulting increase in the AMP. Given the structure of the rebate, it reflects the increased costs that minimize the impact of the rebate. The result is a higher price in the institutional market, as well as a reduced quantity sold in that market.

As shown by equation (6) the post-rebate Medicaid price will exceed the AMP so long as the retail (non-discounted) share of the market is less than 50 percent (assuming that the retail price exceeds the AMP by at least 50 percent).

¹⁸ The Medicare rebate formula proposed under the Health Security Act would have resulted in a more substantial discount. The Medicare rebate would be the greater of (1) 17 percent of the average manufacturer retail price of \$1.00, or \$0.17, and (2) the difference between the AMR of \$1.00 and the average non-retail price of \$0.70, or \$0.30. Because the rebate is not related to the average of retail and non-retail prices, the Medicare price would never exceed the average manufacturer non-retail price.

¹⁹ Strictly speaking, the rebate does not affect the firm’s marginal costs, since these costs have been incurred *ex post* and the rebate is collected *ex ante*. However, if the marginal cost curve is assumed to represent *imputed* marginal costs, then this analysis is appropriate. The application of an imputed marginal costs reflects manufacturers’ estimates of rebate costs that will be incurred as a result of supplying to Medicaid or, if appropriate, Medicare beneficiaries.

Figure 5.4: Impact of a Medicaid Rebate on Best Price



The small amount of evidence available on the impact of Medicaid drug rebate suggests that drug manufacturers did indeed change their discounting practices in the way suggested by economic theory. The U.S. General Accounting Office (GAO) has done the most extensive study of the rebate's impacts on prices charged to the institutional sector. In its most recent analysis, GAO found that by the first quarter of 1993, drugs' average best price discounts to HMOs and hospitals had fallen to about 15 percent below the AMP, so that firms, on average, paid the minimum rebate allowed by law.²⁰ This is exactly the impact that is predicted by the theory.

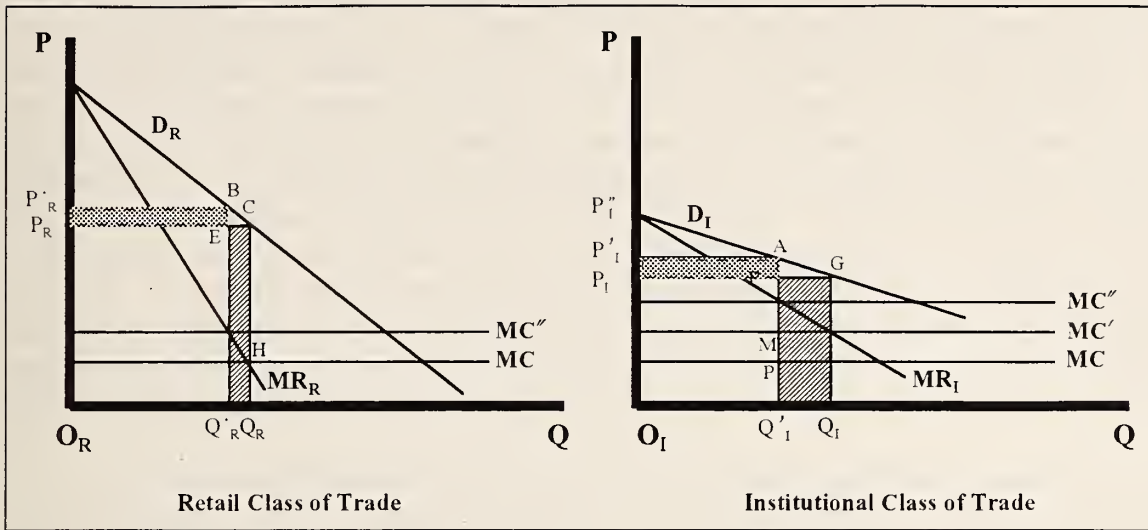
The increase in cost charged to the institutional sector is not the only impact that is predicted by the model. Even by raising the best price, manufacturers would be expected to shift some of the costs of the rebate to the retail sector. Tax shifting is a standard element of economic theory: the long-run incidence of the tax is shared by producers and consumers.²¹ The more inelastic the demand, the greater will be the long-run incidence on consumers.

As is illustrated in Figure 5.5, the rebate/tax leads to an increase in marginal costs in both the retail and the institutional classes of trade. These higher marginal costs result in higher prices in both sectors. The cash paying market will see a price increase to P'_R , while the price for the institutional class of trade will rise to P'_I . Because demand in the retail class of trade is relatively more price inelastic, this increase in marginal costs will lead to a higher price increase in the retail sector than in the institutional sector. If the new relative prices result in a best price that is less than $(1-r)*AMP'$ (where AMP' is the new AMP), then there will be an additional price increase in the institutional market.

²⁰ GAO examined prices on 408 drug products. Data on best price and AMP were provided by the Department of Health and Human Services. Data on prices paid by HMOs and hospitals were obtained from four HMOs and eight Group Purchasing Organization (GPOs), which typically represent many hospitals in negotiating prices with drug manufacturers. The HMOs represented 22 percent of the approximate 38.6 million U.S. enrollees in HMOs, and the GPOs covered about 55 percent of the approximate 6,500 nonfederal U.S. hospitals. See U.S. General Accounting Office, *Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals*, GAO/HEHS-95/194FS (August 1994).

²¹ For example, see Binger and Hoffman (1988).

Figure 5.5: Impact of Cost Shifting on Medicaid Rebate



The price increase has the effect of shifting part of the rebate's costs from manufacturers to consumers. Prior to the rebate, total manufacturer revenues are shown in Figure 5.5 as $O_R P_R C Q_R$ (from sales in the retail class of trade) and $O_I P_I G Q_I$ (from sales to the institutional class of trade). In Figure 5.5, the black shaded areas $P_R P'_R B E$ (in the retail sector) and $P_I P'_I A G$ (in the institutional sector) represent the extent to which rebate costs are shifted to consumers and payers as prices increase (this is in addition to the area $LMNP$ from the previously described reduction in discounts that occurs in the institutional market to reduce the rebate's costs). These areas represent the part of the rebate costs that are indirectly paid by consumers. Manufacturers have not shifted all of the rebate's costs in this example, since they incur reduced profits both from the payment of the rebate and from the reduction in quantity of drugs purchased. These lost profits are shown by the gray areas in Figure 5.6. So long as these areas exceed the increased consumer costs, the manufacturers will bear some share of the rebate. Finally, the rebate results in a loss of consumer surplus, shown by the areas EBC in the retail sector and AFG in the institutional sector.

Note that the price increase in the retail sector results in an increase in the pre-rebate price for Medicaid, since Medicaid beneficiaries are assumed to obtain their drugs in the retail sector. This means that the post-rebate price will be higher than that originally envisioned by the government. Similarly, a drug rebate implemented as part of a Medicare drug benefit would result in an increase in the costs of a pre-Medicare rebate cost of drugs. If consumers had to make a copayment, as was required under most of the proposals before Congress during the 1994 health reform debate, then consumer copayments would have risen as well. Therefore, the government savings from the rebate would have been partially financed by increases in out-of-pocket costs of Medicare beneficiaries.

In contrast to the evidence on price increases to the institutional sector, there is little evidence available to evaluate the magnitude of price increases described above. There has been little, if any, empirical study of the impact of this aspect of the rebate's impact. Theoretically, one might expect the impact of a Medicaid rebate to be relatively small, given the small share of the Medicaid market. Medicaid pays for only about 15 percent of outpatient prescription drug sales, and a 15 percent rebate on originator drugs and an 11 percent rebate on generic products would therefore reduce drug manufacturers' revenues about 2 percent. Given that some of this amount may be recaptured by charging higher prices to the institutional class of trade, it is possible that the impact on firms is even smaller. However, a Medicare rebate would have had much greater ramifications. The over-65 population currently account for about one-third of outpatient prescription drug costs; this share might be expected to rise as a result of increased coverage. Applying a 17 percent rebate on originator drugs to one-third of the market could cause as much as a 6 percent drop in drug manufacturer revenues²². This would likely lead to efforts by drug manufacturers to increase prices charged in an effort to recoup lost revenues.

The impact on prices and quantities will also depend on the relative elasticity of demand for the products. The more elastic the demand, the less manufacturers will be able to pass along rebate costs. Therefore, any cost increases would likely be felt more by the retail class of trade than the institutional class of trade. Furthermore, prices would increase more for drugs for which there are fewer substitutes. Again, the size of the increase will depend on the magnitude of the increase in firms' marginal costs.

In addition, any revenue losses associated with the rebate could be counteracted by a provision in the rebate law that could have led to increases in quantities of drugs sold. Specifically, the law establishing the Medicaid rebate restricted states from placing on the formulary any product sold by a manufacturer that agreed to provide rebates for its products.²³ When the rebate law was implemented, restrictions were lifted in the 20 states which had formularies in place. As a result, demand for those products that were subject to formulary restrictions should have increased. To the extent that the law resulted in this increase in demand, the losses incurred by drug manufacturers would have been reduced.²⁴

Furthermore, it should be noted that not all manufacturers engage in price discrimination. Some manufacturers charge the same price in every market²⁵ and therefore face a larger share of

²² This is likely an overestimate of a Medicare drug rebate's impact on drug manufacturers' revenues. Two factors contributed to this over estimation. First, because about 12 percent of the over-65 population are Medicaid beneficiaries (Long, 1994), drugs they receive have already been subjected to a Medicaid rebate; manufacturers have already felt the impact of those lost revenues. Second, the rebate would accompany a Medicare drug benefit that would increase manufacturer revenues above current levels. CBO estimated that the demand would increase by 4 percent under the benefit proposed in the Health Security Act.

²³ This restriction was modified as part of the Omnibus Budget Reconciliation Act of 1993, which gave states the authority to establish formularies even when rebates are in place (NPC, 1994).

²⁴ By contrast, demand might fall for drugs that had been substituted for products that faced formulary restrictions.

²⁵ For example, the president of pharmaceutical manufacturer Merck stated during testimony before the Senate Aging Committee that his company does not negotiate discounts with HMOs and hospitals. Companies that can effectively practice a single pricing policy are those that either have many products with few therapeutic substitutes, or that have several such products in the pipeline.

the market that is relatively price inelastic. These firms would not be raising prices to the institutional sector any more than they would raise them to the retail sector, and may be less affected by rebates than by other types of cost control policies.

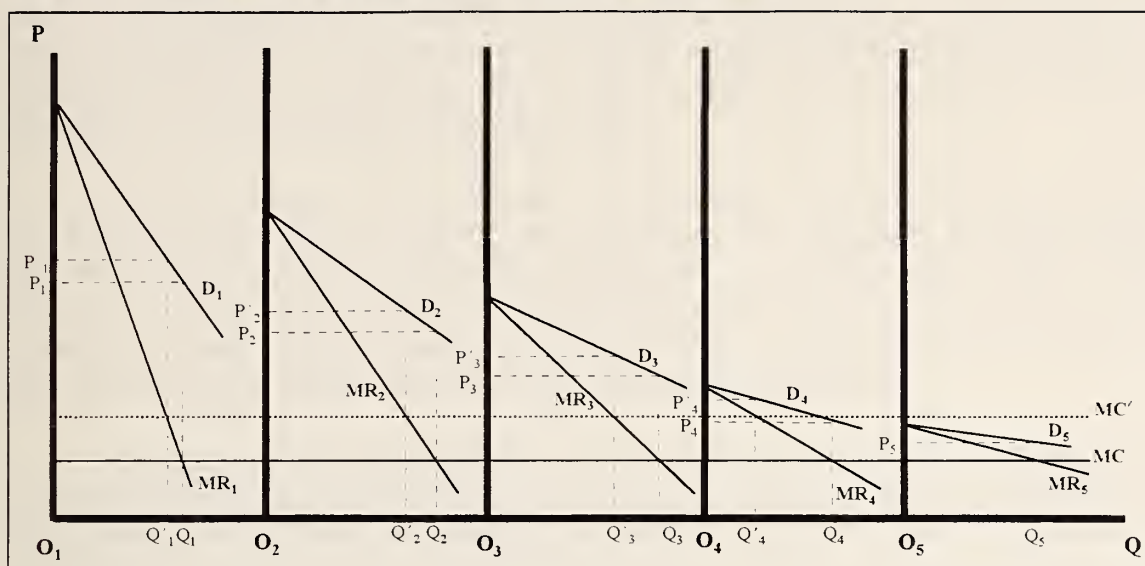
Impact of the rebate on competitive forces in the pharmaceutical market. An additional concern regarding the Medicaid rebate is that the reduction in manufacturer profits associated with the rebate may lead manufacturers to drop out of existing markets, reduce overall R&D efforts, and reduce the rate of product development. This impact would slow the introduction of new drugs and decrease competitive forces that, by themselves, lead to reductions in prescription drug prices. As is shown in the following discussion, these arguments can be supported by the conceptual model we describe. However, the magnitude of the impact is likely to vary with the size of the program being affected. The Medicaid drug rebate, which affects a relatively small share of the market, may have an impact only on those products which are only marginally profitable without the rebate. A Medicare drug rebate, affecting a much greater share of the market, would have much greater effects. In addition, the impact would be greatest on those drugs that have very high levels of utilization by the elderly.

Potential impact on existing products. In the preceding discussion of the rebate, we have--for ease of exposition--been focusing on the market for a single product to describe the rebate's impacts. However, as was discussed in the development of the conceptual model, pharmaceutical manufacturers are engaged in multi-product production. These products range in levels of profitability. An illustration of a product line for a hypothetical firm is given in Figure 5.6. In this illustration, the firm produces five products, numbered 1 through 5. Product 1 is the most profitable, and Product 5 is the least profitable, providing a very low profit margin. For the sake of illustration, we have not separated the market for each product according to class of trade. Therefore, the demand and marginal revenue curves for each product can be thought of as average market prices.

Assume that a rebate imposed on pharmaceutical products sold to Medicaid raises the firm's marginal cost to MC' . Production of all products would change; the firm would equate its new marginal costs to the existing marginal revenue curve it faces, resulting in decreased quantities and increased prices for Products 1 through 5. For Product 5, however, there is no output which would result in profits. The firm would either continue producing Product 5 at a loss (it may do so if it enhances revenues by offering firms a complete product line) or will stop production of that product.

The impact of having Product 5 exit the market depends on its market share. If Product 5 held a significant share of the market for this product line, then the exit of the drug from the market could result in price increases by other manufacturers--clearly an undesirable effect. However, Product 5 had a small share of its market, then the remaining manufacturers might be sufficiently competitive to absorb this firm's market share without increasing prices.

Figure 5.6: Impact of a Rebate on a Multiproduct Firm



Is it reasonable to expect that the Medicaid rebate would lead products to leave the market? Not only would the increase in marginal costs have to be sufficiently large to make a product unprofitable, but the product's profitability would have to be extremely low to be affected by a rebate that--as mentioned earlier--might affect (at most) about 2 percent of total revenues. Given the low marginal costs of producing drugs relative to the sales price, it may be unlikely that a rebate affecting the Medicaid sector would be large enough to make a drug unprofitable. Even if it did lead manufacturers to drop products from the market, the impact on prices would depend on the market share of the drug being discontinued. If this firm's Product 5 is a small share of the market in this therapeutic category, then the impact on prices is probably negligible. If, however, it was a large share of the market, then the impact would be much more substantial.

The impact of a Medicare drug rebate would be much more substantial, particularly if Product 5 was a drug used frequently by the elderly. In this case, it is more reasonable to assume that the increase in marginal costs--the cost of paying the rebate--could lead to a sufficiently high level of marginal costs that would lead manufacturers to leave the market.

Whatever impact occurs may be greater for generic drugs than for products of branded companies, when a generic drug rebate is part of the drug payment mechanism. Although the Medicaid rebate is lower for generic drugs than for branded products, the impact on generic firms may be even more significant if generic drug manufacturers earn substantially lower profit margins. A 1992 analysis of the impact of the Medicaid rebate found that the rebate, in its first year of implementation, decreased the average generic firm's net income from 2.97% to 2.05% of sales revenue, while the typical originator firm's net income decreased from 15.00% to 13.98% of sales revenue (Schnodelmeyer, 1992). There have not been any more recent studies on whether this trend still holds. But if the relative profit margins between brand and generic firms have remained unchanged, and if the marginal costs of generic and innovator manufacturers are approximately the same, then the rebates take a higher share of generic drug profits than they do

for brand name firms. Furthermore, generic firms may be less able to pass on price increases due to the competitiveness of the industry and the inability of generic firms to differentiate products. (In the brand industry, it may be easier to increase prices on some products because of real or perceived differences in products. For instance, a drug may have fewer side effects than a substitute, or a reduced number of doses per day).

Potential Impact on Future Product Development. A prescription drug rebate not only reduces revenue on current products, but also reduces the profitability of future products. The reduced revenue stream can enter into manufacturers' calculations about whether and how to invest in future products. If the rebate is sufficiently large, it may inhibit the ability of marginally profitable innovative manufacturers to continue their drug development activities and the ability of marginally profitable generic drug manufacturers to continue producing.

As discussed in the presentation of the conceptual model, drug manufacturers must continually develop new products in order to remain competitive. This means that the revenues must equal or exceed long run average costs, which include the costs of production that are considered fixed in the short run. These costs are high at low quantities, but fall with an increase in output. As shown in Figure 5.7, if long run average costs are LRAC, and the average price received by the manufacturer is P^* , then the firm will be able to operate profitably so long as output exceeds Q_1^* . However, if the rebate results in a shift of the long run costs to $LRAC'$, then the minimum profitable output level rises to Q_2^* . Any firm operating at an output level between Q_1^* and Q_2^* (for average price P^*) will find operation unprofitable in the long run (as long as the mix of goods sold remains unchanged). This effect would be compounded if additional market pressures, such as the increased role of managed care in the distribution of prescription drugs, leads to downward pressure of the average price P^* .

In order for firms to drop out of the market, either the rebate would have to result in a substantial increase in costs or the firm would have to be only marginally profitable. Given the high profits enjoyed by most pharmaceutical firms, it is unlikely that the Medicaid rebate, by itself, would affect the ability of most manufacturers to continue their R&D activities. The impact might be greater for less profitable generic manufacturers, but an analysis of the impact would require obtaining information on the profitability of individual firms. However, a Medicare rebate would be expected to have a much more substantial effect on both innovator and generic manufacturers.

A second potential long run impact of the rebate would be in raising the threshold by which firms decide to put resources into new drug development. The impact of a Medicaid rebate is likely to be the same for all products, although if there were drugs that were specifically targeted to the Medicaid population, the impact would be greater for those products. For instance, if products had to earn \$100 million in annual revenues to be considered a worthy investment, the rebate might raise the threshold to a level which covers expected rebate costs. This is shown in Figure 5.8.

Figure 5.7: Long Run Average Cost

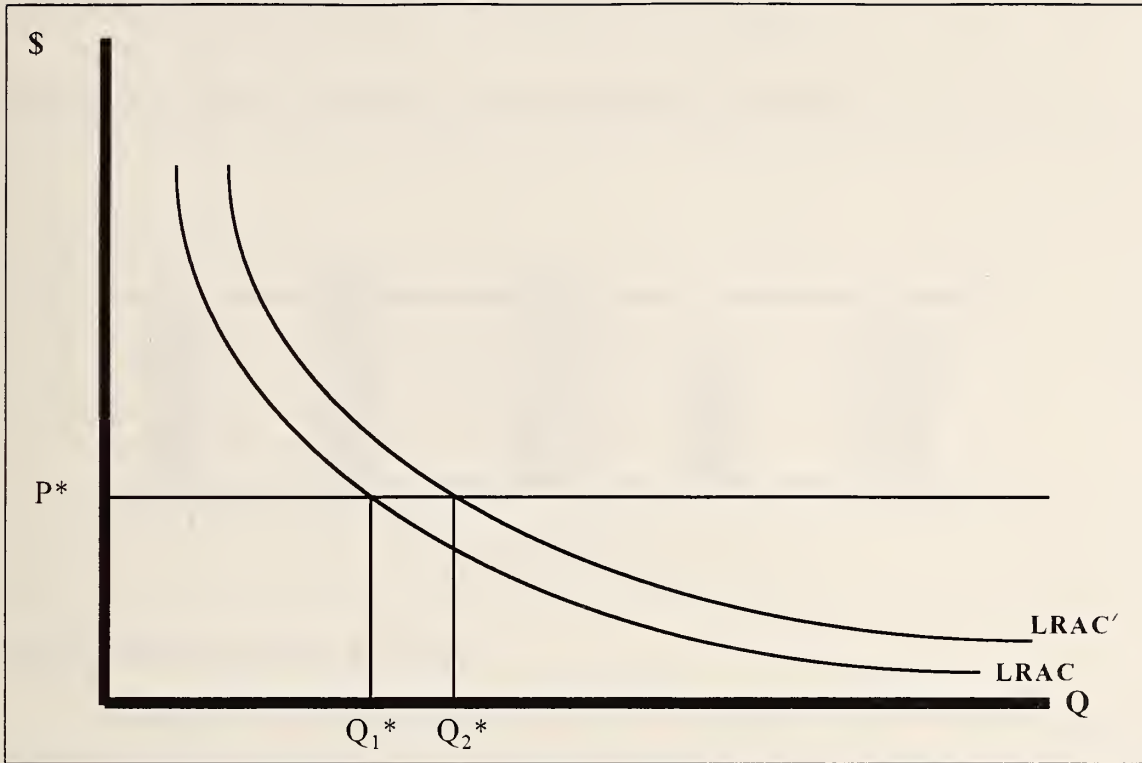
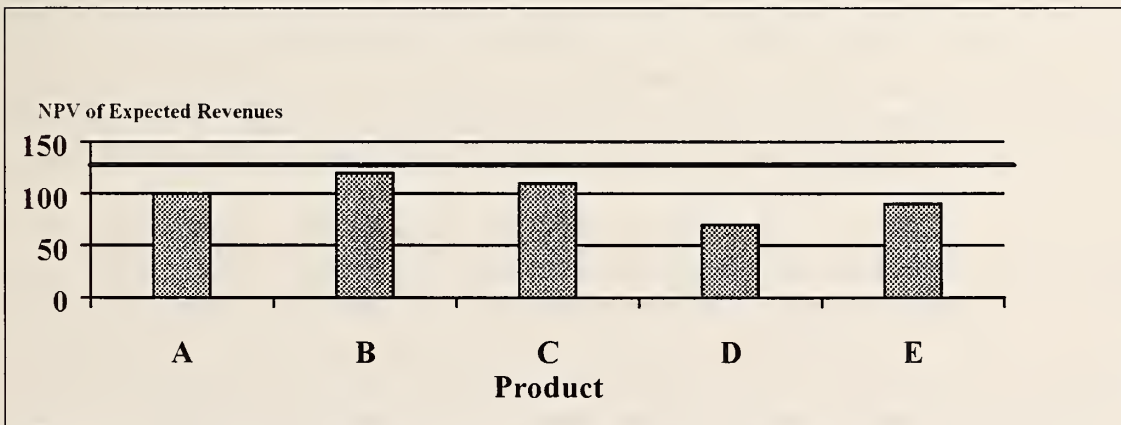


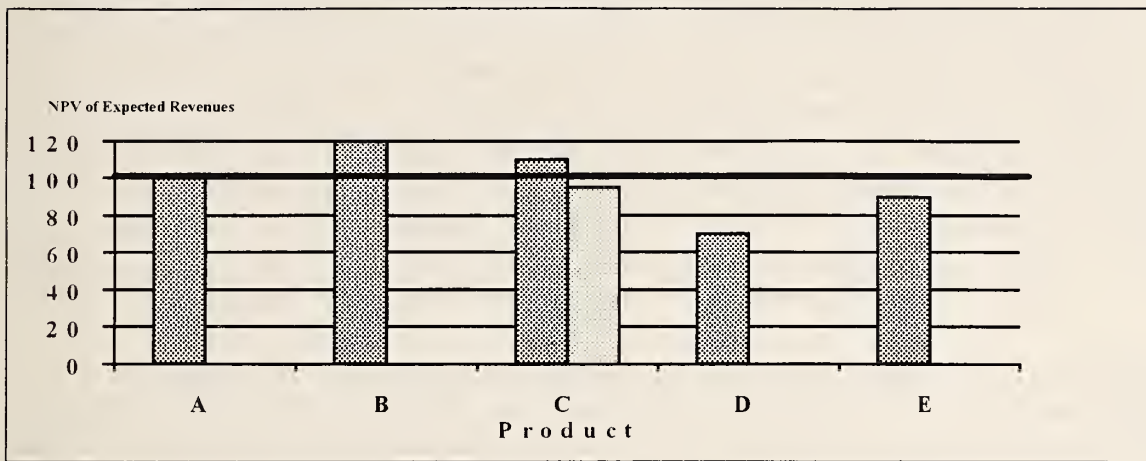
Figure 5.8: R&D Decisions of the Pharmaceutical Manufacturer



However, a rebate applied to Medicare would be expected to affect drugs for the elderly more than those used for the general population, because the rebate would apply to virtually all of the particular product volume sold in the U.S. This might, for instance, reduce incentives to develop drugs to treat arthritis, osteoporosis, and Alzheimer's Disease. Suppose, for example, that Product C is a treatment for osteoporosis. A Medicare rebate might reduce the estimated revenues to \$95 million. As shown in Figure 5.9, this might lead the firm to decide that the

estimated revenues are below the estimated costs, and lead it to reconsider or postpone its decision on whether to proceed with development of this drug.

Figure 5.9: Impact of a Rebate on Expected Revenue Stream



Marketwide Direct Price Controls

In contrast to a policy such as the manufacturer rebate, a direct price control is used to establish drug prices nationwide. As used in the prescription drug market, these prices are either set by the government or determined in negotiations with drug manufacturers. Price controls have not been widely used in the United States during peacetime, with the notable recent exceptions of the federal wage and price controls that were applied in the early 1970s. But market-wide price controls for health services--and for prescription drugs in particular--have been used in a number of countries that have single-payer or national health insurance systems.²⁶ If a single-payer health system were ever to be considered in the United States, then price controls on prescription drugs might be one reimbursement policy that may be considered. For this reason, it is important to analyze its effects within the context of the existing health care marketplace.

The stringency of the system may vary from country to country, particularly regarding how low prices are and whether price increases are allowed. For example, Sweden generally tried to negotiate prices that were at about the median price among members of the European Community (GAO, 1994a) while prices in France, Greece, Italy, and Spain have achieved price levels that are among the lowest in Europe (Redwood, 1992). A direct price control can limit all drug price increases, can keep price increases within a certain target (e.g., within the rate of inflation), or can even order global price reductions, as occurred in France in 1991.

²⁶ Examples of industrialized countries in which the central government sets or negotiates nationwide prescription drug prices include France, Greece, Italy, and Spain. See Redwood (1995).

Analysis of Impact of Price Controls

Short-run impact of price controls. The introduction of some sort of direct price control--whether achieved by negotiation or government fiat--has the potential to greatly reduce the cost of the government program. For example, assume that the government agrees to pay a unit price of $P_G < P_1$ for the drug and consumers continue to have no cost-sharing requirement. This is shown in Figure 5.10, where P_G represents the price set by the government. As long as the price, P_G , exceeds the marginal cost of production, the manufacturer will agree to supply whatever quantity is demanded of this drug, in this case, Q_2 (assuming constant marginal costs at this level of output). Since the effective price to consumers is still zero, quantity demanded will remain at Q_{\max} . However, the price reduction reduces total government costs from area OP_1CQ_{\max} to $P_1P_GJQ_{\max}$. This results in a reduction in manufacturer revenues of area P_1P_GCJ . Consumer benefits are unchanged, while the excess government cost is reduced to area HJQ_{\max} .

The magnitude of these impacts depends on how strictly these controls are applied. The existence of a price control does not necessarily imply that prices will be significantly lower than what would be charged in the absence of regulation, especially if the control is being applied in the absence of observations about market behavior. For example, the government may set a price that is near, at, or even above P_1 , without realizing that the market would set a similar or even lower price if left to its own devices. However, the price setting agency may seek to avoid this by setting a price in relation to prices charged in other countries (in effect, using those prices as a gauge of market value), or by requiring manufacturers to submit data on the product's cost effectiveness relative to alternative treatments.

Intermediate and long -run impacts of price controls. Over time, price controls can affect the pharmaceutical market in ways that are unanticipated and can adversely affect consumers in the long run. First, while keeping prices lower on products, they also may inhibit entry of competing products. As was shown in Chapter 4, competitive forces can bring reductions in prescription drug prices when similar products are on the market. This competition works most effectively when third-party payers have both the knowledge base to restrict drug consumption, and are able to manage drug costs by restricting utilization of higher-priced products--conditions that exist in the managed care sector in the United States.

By reducing the profits that are earned from sales before competitors are on the market, a price control limits the incentives for introducing competing products. When a drug is earning excess economic profits, then there will be an incentive for other manufacturers to enter the market. In addition, later entrants sometimes offer therapeutic improvements over existing products.²⁷ To the extent that buyers are prudent, the increased number of drugs on the market can lead to a bidding down of prices (at least to those sectors that are managed). However, if potential market entrants see that profits reduced, there will be a slowing of entry of potential competitors. The magnitude of this impact depends on how low a price is set and the extent to which excess profits remain.

²⁷ While some of these latter-entry products are appropriately called "me-too" products, others offer improvements that are beneficial to patients.

To the extent that competition (rather than regulation) causes price reductions, it decreases the welfare loss from that which occurs under price controls. Turning to Figure 5.11, suppose that competitive forces eventually lead to a price which, in the absence of government intervention, was P_2 . While per unit costs would still be higher than under the regulated price P_G , total expenditures could be reduced relative to the regulated price (from OP_GCE to OP_2BF) because the higher price would lead to a drop in consumption from Q_{\max} to Q_2 . The price P_2 also results in both reduced welfare loss as well as a reduction in consumer value obtained. The loss in consumer welfare is an important consideration if the level of medically necessary drugs exceeds Q_2 . However, if Q_2 exceeds this level, then such a decrease is not optimal.

Price regulations can also affect the profitability of drug manufacturers, as well as their decisions on drug development. One set of impacts on regulated prices can occur if prices are not allowed to increase as quickly as input costs. Some regulations, such as those in France and the United Kingdom,²⁸ largely prohibit drug manufacturers from raising drug prices. If manufacturer prices are not allowed to reflect increases in labor, material, or manufacturer costs, then profits are reduced. The effects of these restraints are illustrated in Figure 5.12, which shows successive increase in marginal costs over time, as represented by the marginal cost curves MC' , MC'' , and MC''' . Each increase in costs, unaccompanied by price increases, results in successive reductions in manufacturer profits. To the extent that marginal costs rise significantly, the reduced profit levels in this market further limits entry by competitors and, after patent expiration, generic entrants if prices are so low that generics could not profitably offer a significant price advantage. Eventually, the drug itself could be unprofitable to produce.

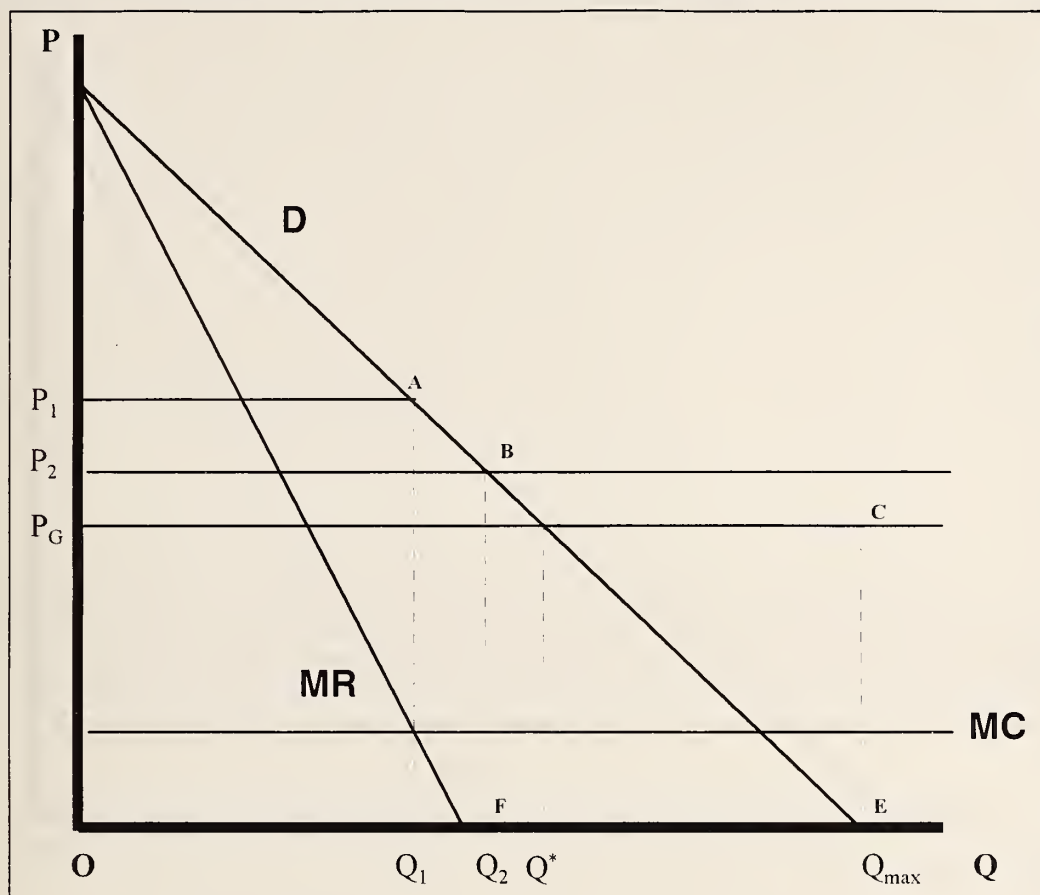
The extent to which input costs actually impede drug development depends on the level of marginal costs and their growth over time. Since marginal costs of drug manufacturing are assumed to be quite small--most of the firm's costs being taken up by R&D and marketing--it is possible that these effects would be trivial. However, price controls may affect firms' ability to continue the R&D activities required to stay competitive. As was discussed in Chapter 4, drug manufacturers must expend large amounts of money and absorb high levels of risk in order to develop new products to replace those that become obsolete or lose market share to generic and innovative competitors. These expenditures do not even guarantee continued success, since it is difficult to predict in advance whether or not expenditures will lead to a drug that is safe, efficacious, and marketable.

Figure 5.13 shows a drug manufacturer's long-run average cost curve (LRAC). This long run average cost curve reflects the costs of R&D marketing expenses that are variable in the long run, but which are considered fixed in the short-run and therefore are not reflected in short-run marginal cost curves. To remain profitable, the average price received by the manufacturer for drugs it sells must exceed the LRAC at the quantity being sold. For example, at market prices P_1 , the firm must sell at least Q_1 in order to be profitable in the long run. At quantity Q_{max} , which corresponds to the maximum consumer demand in Figure 5.10, firm profits are relatively substantial. But when government price regulations reduce prices, the profits can fall substantially, depending on how much prices are lowered. In this example, lowering average prices to P_G leads to a requirement that firms must sell at least Q_G to be profitable. In this example, the manufacturer would still be profitable at Q_{max} , which corresponds to a zero effective copayment. But if the copayment rose to a level that led sales to fall below Q_G , then the firm could not operate profitably in the long run.

²⁸ While new drug prices are not regulated in the United Kingdom, prices on existing products are generally not allowed to rise without permission from the government (GAO, 1994a).



Figure 5.11: Comparison of Direct Price Control to Market-Driven Price Reduction



Finally, the price controls change the incentives for pharmaceutical R&D, both in terms of the drugs in which research should be focused and in manufacturers' ability to develop drugs needed to remain viable in the future. First, by reducing manufacturer prices, the regulations reduce the incentive to develop any single product--particularly those which are only profitable at the margin. Second, if the regulations reduce the returns on newer, more innovative and more profitable drugs more than those that are less profitable, they can lead to relatively more development of less innovative products. Third, by reducing overall revenues to manufacturers, the regulations may make it difficult for manufacturers to support the R&D activities required to remain competitive. This final impact could be lessened, however, to the extent that product lives on existing products are extended, thereby decreasing the financial need of manufacturers to develop new products.

Figure 5.14 shows an example of how the first two of these impacts may affect a firm's R&D decisions. The darker bars in Figure 5.14 show the expected lifetime revenues under an unregulated pricing system for a hypothetical set of drugs currently under development. As was discussed in Chapter 4, product A is a drug that is expected to offer major therapeutic improvements over existing treatments; products B and C are expected to offer moderate

Figure 5.12: Impact of Input Cost Increases When Prices are Regulated

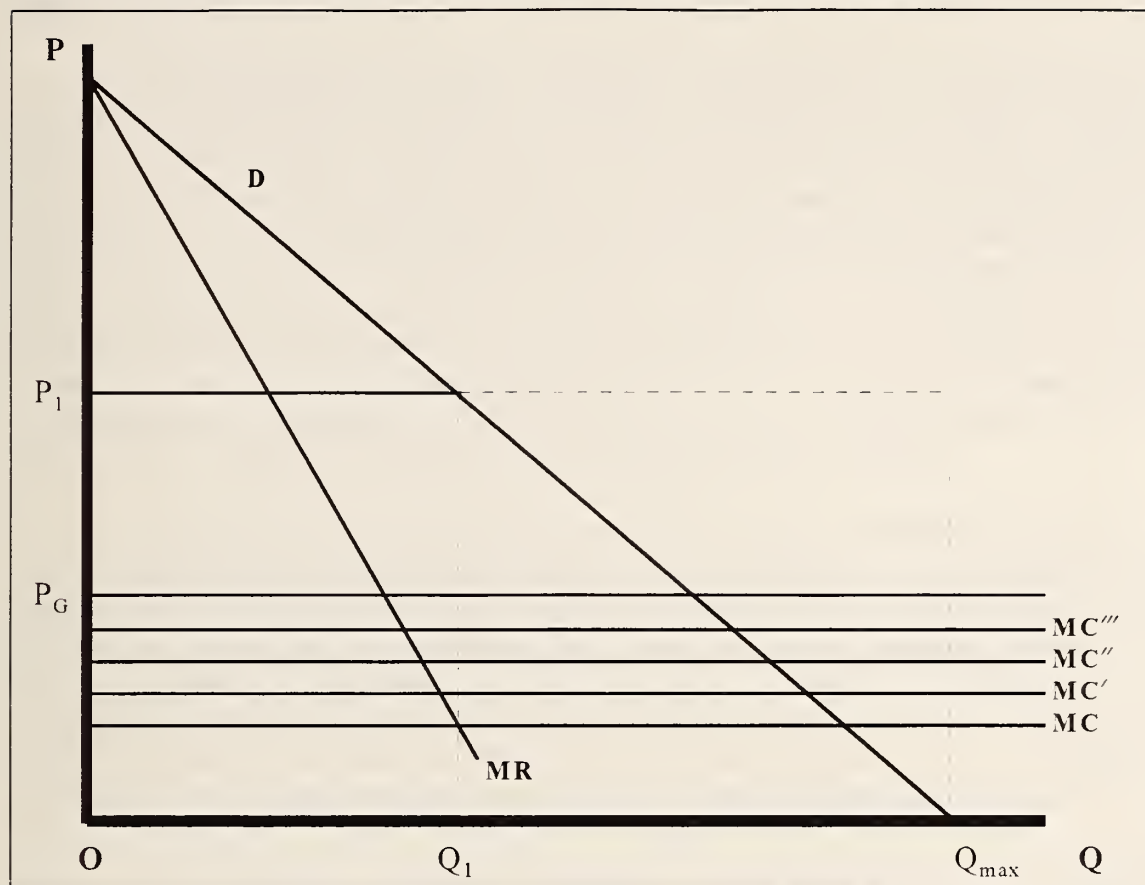
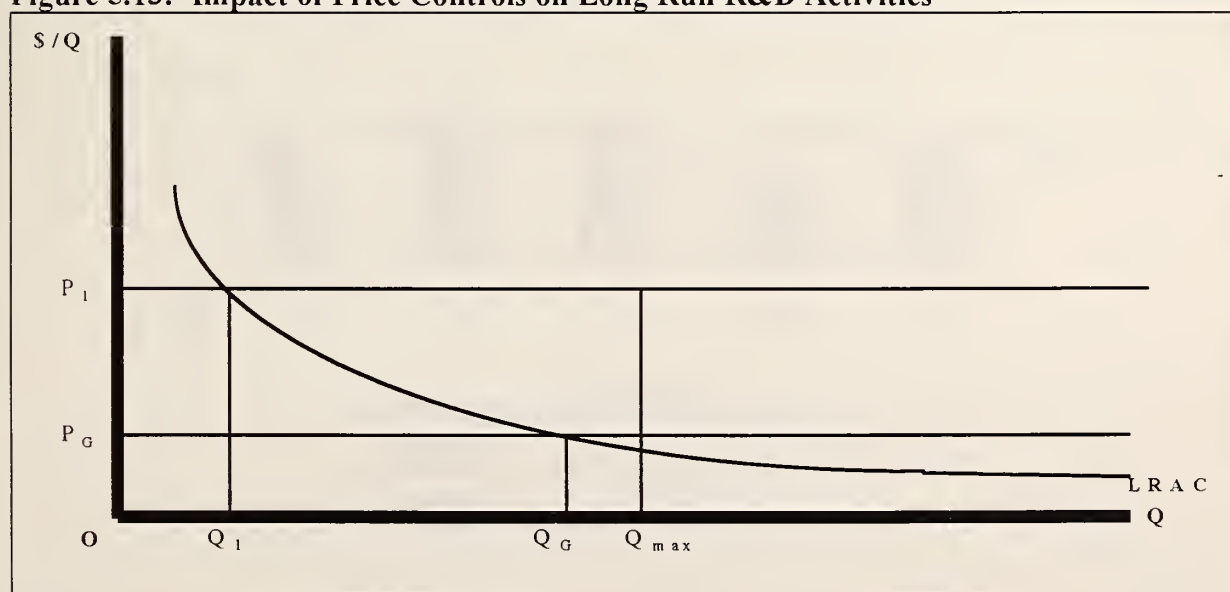


Figure 5.13: Impact of Price Controls on Long Run R&D Activities

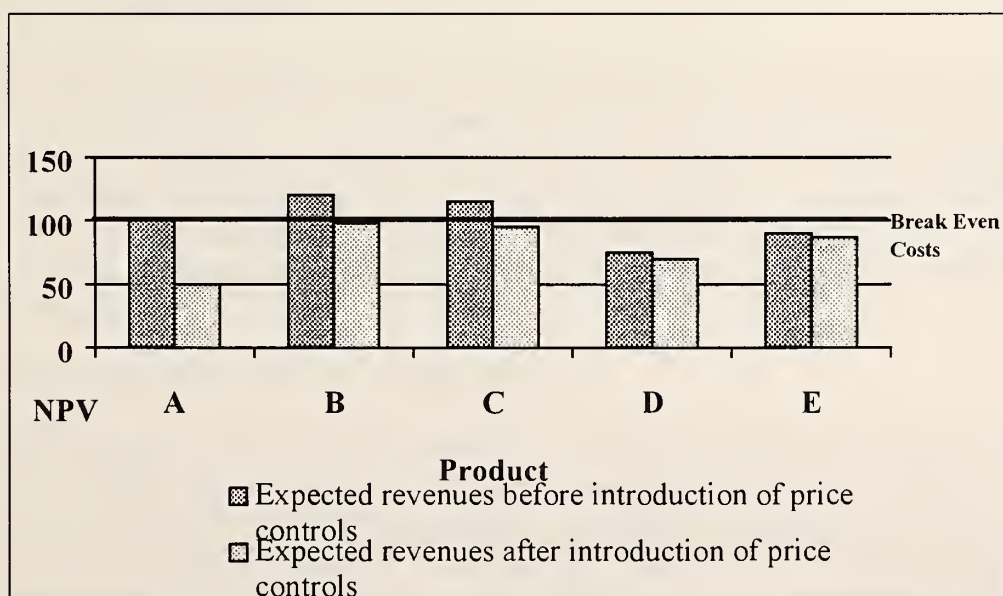


therapeutic improvements; and products D and E are expected to offer minor therapeutic improvements.

The existence of a price control is expected to have a downward impact on the net present value of expected lifetime revenues for these drugs. In addition, the decrease is expected to be greater for some products than for others. It is assumed the type of price regulation being considered in this example will affect Drug A (the drug representing a major therapeutic advance) more than for the other drugs, because the lack of substitutes for drug A would have allowed the manufacturer to charge a much higher price as a percent of the allowable government price. (That is, the difference between the regulated and unregulated prices is expected to be higher for Drug A than for the other products.) It is important to note that the actual impact exhibited here is unique to the type of control being considered. In some circumstances, revenues might not fall as significantly as pictured here, might fall less for major improvements than for minor improvements, or might rise due to an extension of expected product life.

In this example, the firm finds that Drug A is no longer profitable to produce. While in actual production Drug A might be profitable, recall from Chapter 4 that this chart considers the *expected value* of each drug, which incorporates assumptions about the probability of the drug reaching the market, and the probability that a major therapeutic advance will reach the market before the advances of competitors. Since the firm is assumed to face a high risk of Drug A reaching the market, its expected value is far less than its actual value if it reaches the market. Because the price that would be allowed for this drug is perceived to be relatively low, the manufacturer in this example finds that the cost of developing the product exceeds its expected value.

Figure 5.14: Impact of Price Controls on R&D Decisions of Pharmaceutical Manufacturers



Drug Price Review Boards

Relative to marketwide price controls, drug price review boards are a more limited type of price control on prescription drugs. Drug price review boards are used to regulate both launch prices of new drugs and price increases on existing products. As applied in Canada and proposed in the U.S. (and as noted in Chapter 2), they differ from direct price controls in several ways.

- The boards do not have jurisdiction over all drugs sold. Regulations of Canada's Patented Medicine Prices Review Board (PMPRB) are limited to patented drugs for which lower-priced generic substitutes cannot be offered. The Advisory Council on Breakthrough Drugs proposed in the United States would only apply to products that did not have therapeutic substitutes.
- The boards have limited enforcement power. In both the Canadian and the American example, price approval is not required for putting a drug on the market. While the Canadian PMPRB has some authority to achieve compliance with the guidelines once a product has been on the market, the Advisory Council on Breakthrough Drugs would have no compliance authority. By contrast, countries with price controls often require that the government approve the price before the drug is sold on the market.
- The board sets pricing guidelines on *excessive* prices, rather than limits on what is *fair* or *reasonable* prices. This subtle but important distinction relates to a concern that drugs lacking in product competition can earn monopoly profits for manufacturers. The emphasis on "excessive" prices is intended to allow some level of pricing freedom without allowing prices to rise to what the government considers to be extremely high levels.
- Because pricing guidelines may be relatively high, they do not necessarily represent a floor. Particularly in the Canadian case, where patented products may have non-generic therapeutic substitutes that represent competition for patented products, the guidelines may represent more of a floor than a ceiling. An example illustrating this point is that patented drug prices in Canada declined between 1993 and 1994, even though the pricing guidelines allowed them to rise at the annual CPI increase of 0.19 percent.²⁹

Impacts of a Price Review Board on Patented Drugs

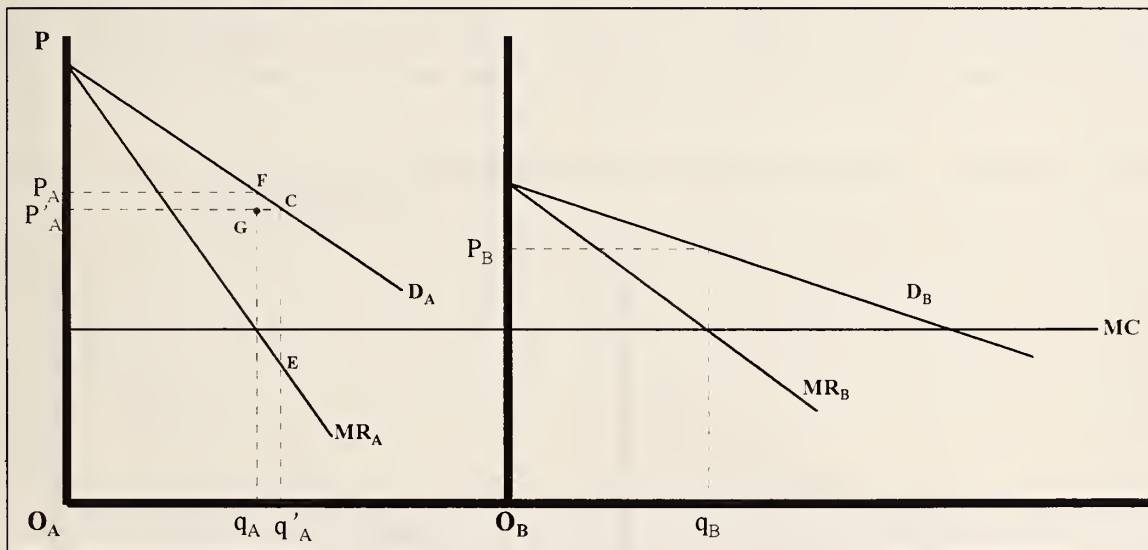
Initial impacts of a drug price review board. Figure 5.15 illustrates how the conceptual model of the pharmaceutical market can be used to analyze the immediate impact of a price review board. In Figure 5.15, we show the impact on a typical drug manufacturer which, for the sake of simplicity, is assumed to produce two drugs (or, to generalize, two *types* of drugs)--those under patent (drug A) and those not under patent (drug B). Prior to the introduction of a price

²⁹ Patented Medicine Prices Review Board, *Seventh Annual Report: For the Year Ended December 31, 1994* (May 1995)

review board, the drug manufacturer--a profit maximizing producer with some degree of monopoly power in the market--chooses price and output by equating marginal revenues to marginal costs (for ease of exposition, it is assumed that the manufacturer sells to only one market segment. This assumption will be relaxed later). The market prices of these drugs are P_A and P_B , with corresponding market quantities of Q_A and Q_B .

The introduction of a price review board for patented drugs will affect only the market for product A. The price review board will evaluate the market price P_A based on the criteria it has established for an allowable price. If P_A falls within these guidelines, then the board will, in effect, have no impact on the market. However, if the allowable price is P'_A , then the manufacturer will be required to lower its price. As shown in Figure 5.15, this regulation changes the demand and marginal revenue curves faced by the firm. The new demand curve becomes the kinked line $P'_A C D_A$, representing the requirement that regulations restrict the price from rising above P'_A at quantities below q'_A , and that market forces keep prices below P'_A at quantities above q'_A . The marginal revenue curve is the same as the demand curve at quantities below q'_A --since marginal revenue equals price at those levels of consumption--and then becomes discontinuous, corresponding to the original marginal revenue curve at q'_A .

Figure 5.15: Impact of a Drug Price Review Board on Prices Charged by Drug Manufacturers



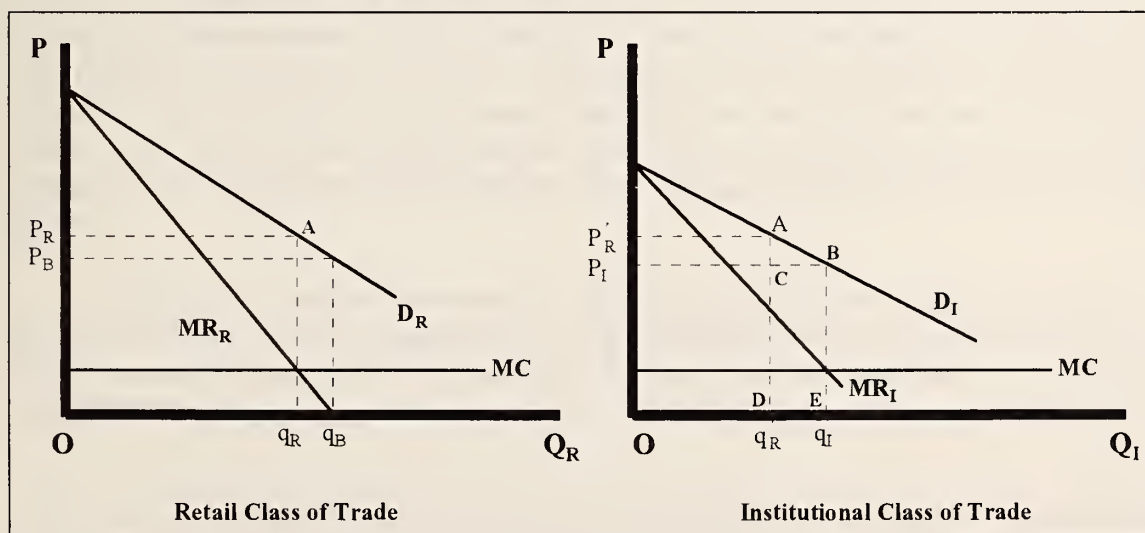
After the Board's ruling, the manufacturer will maximize profits by producing at q'_A . The manufacturer will experience a net revenue loss of area $P'_A P_A F G$ less area $q_A G C q'_A$. Note that, depending on how much prices fall and quantities rise (that is, depending on the magnitude of the price drop and the elasticity of demand), the firm might still have a net revenue gain if the Board's creation is accompanied by policies that increased product demand. For example, drug manufacturers selling patented products in Canada likely experienced such an increase because establishment of the Canadian drug price review board accompanied changes in patent laws that gave patented drugs market exclusivity that they had previously lacked (that is, drugs covered

under the Board's jurisdiction no longer faced generic competitors). In the United States, firms would likely have experienced an increase in demand because the proposed price review board would have accompanied the provision of universal prescription drug coverage.

Impact on price review boards to the institutional sector. One potential criticism of a price review board is that manufacturers may try to shift the cost of the board's impacts onto the institutional class of trade. Specifically, there may be a concern that regulations requiring firms to reduce the prices charged in the retail class of trade may lead manufacturers to increase prices charged to the institutional class of trade in an effort to recoup lost revenues. If true, this trend would reduce the rewards for efficient purchasing practices that accrue to the institutional purchasers. However, our conceptual model suggests that it would be difficult for drug manufacturers to shift the cost of the price guidelines to the institutional class of trade, at least in the short run.

The analysis leading to this conclusion is illustrated in Figure 5.16, which shows the markets for a typical drug in both the retail and institutional class of trade. Prior to the establishment of a price review board, the firm sets price and quantity for each market at the point where each sector's marginal revenue curve equals the firm's marginal cost: P_R and q_R in the retail class of trade, and P_I and q_I in the institutional class of trade. Note that the price in the institutional class of trade is less than the price suggested by the board guidelines. We are assuming that the institutional sector is able to apply prudent purchasing practices to obtain discounts not available to the retail class of trade. In this case, the board's guidelines will lower prices in the retail class of trade but have no impact on prices in the institutional class of trade.

Figure 5.16: Impact of a Drug Price Review Board on Prices Charged to Different Classes of Trade



Suppose that a price review board sets regulations such that the price for the drug cannot exceed P_B , such that $P_I < P_B < P_R$. In this case, the price in the retail class of trade will be required

to fall; as shown in Figure 5.16, the firm maximizes revenues by selling at q_B and price P_B . While manufacturers might want to increase the price charged in the institutional class of trade in order to gain some of its lost revenues (if, indeed, it has lost revenues), market conditions will not allow it to do so. As can be seen by examining the right side panel of Figure 5.16, the firm would reduce its revenues by raising prices above P_i ; revenues would fall by area CBDE less P_RACP_i .³⁰

Impact of regulations that restrict price increases. Price review boards could regulate allowable price increases as well as launch prices. For example, Canada's drug price review board ties allowable price increases on patented drugs to the growth in the Consumer Price Index (CPI).³¹ If these regulations are not binding--that is, if market forces prevent prices on particular products from rising as fast as the regulations allow--then the regulations have no effect. But if the regulations are binding, they suffer from arbitrariness that could affect the profits earned on particular products. Tying price increases to the growth in general inflation may make the product more or less profitable over time, depending on changes in the cost of production. If production costs for drugs rise less slowly than the general price level, then drug manufacturers will be allowed to increase profits over time. By contrast, if input costs rise faster than the CPI, then profits will fall. At the extreme, prices may not be allowed to rise enough to cover costs, and manufacturers may decide to halt production of drugs that are no longer profitable. However, given that manufacturing costs are relatively low, such an impact may be unlikely. A complete examination of the costs of production to the prices charged is required to give this effect a complete evaluation.

Impact of a price review board on future product development and on competitive forces within the pharmaceutical market. If the price review board does have the effect of reducing drug prices, then it follows that manufacturer revenues will decrease to the extent that the revenues from increased utilization are less than the revenue loss from lowering prices. This will lead to a decreased return on particular products, as well as a decreased overall capacity for firms to engage in pharmaceutical R&D. Specifically, the price review board, by limiting drug prices, may restrict the revenues of all drugs. Depending on market conditions for particular products and the structure of the pricing guidelines, these decreases may be higher for some drugs than for others. (As noted earlier, the net impact may be an increase in revenues and profits if the establishment of the Board is accompanied by an increase in insurance coverage for prescription drugs).

Whether the change in revenues is sufficient to lead firms to halt production of specific products will depend on the magnitude of the price decrease and the demand for each product. If firms decrease research efforts for products, the decreases are most likely to occur in products that face competition from other drugs, since total available revenues are split among several

³⁰ Note that the firm may actually gain revenues after the establishment of the Board, if the added revenues from the increase in quantity demanded that comes from lowering price brings more revenue than the decrease in revenues associated with the price reduction. As with the previous example, this increase is much more likely to occur when the establishment of a price review board accompanies an increase in drug benefit coverage.

³¹ Specifically, the allowable three-year cumulative price increase on a particular drug may not exceed the three-year cumulative growth in the CPI. In addition, one year price increases are limited to 1.5 times the CPI growth (Schulman, 1995).

firms. This would imply not only a decrease in competitive forces that lead to lower priced products without regulation (particularly in the institutional class of trade), but also decreased potential of therapeutic improvements from these latter market entrants. In addition, research might be redirected away from major therapeutic improvements that have a relatively small market.

In addition, if a price review board results in lower manufacturer revenues, it also may reduce the overall ability of firms to engage in pharmaceutical R&D. In considering the impact in this area, it is important to note that innovative drug manufacturers receive most of their revenues from patented drugs (since generic competitors take a large market share once a product's patent has expired). If the price and revenue reductions are substantial, then R&D will be significantly curtailed, harming future drug development.

Impact of a Breakthrough Drug Price Review Board

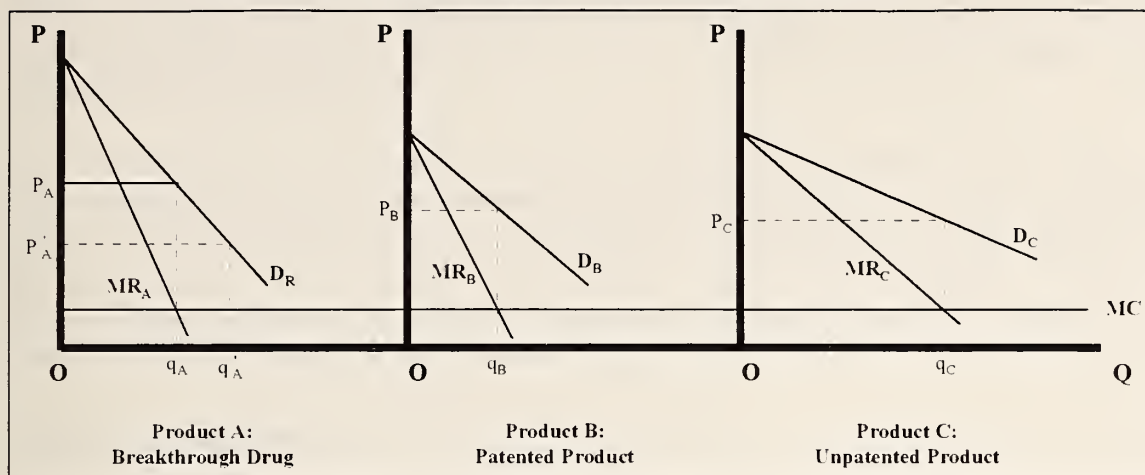
The price review board proposed as part of the Administration's health reform effort differed from the Canadian board in that its jurisdiction was limited to breakthrough drugs. The classification of breakthrough drugs has been used by the FDA to represent a small number of drugs that "represent significant advance over existing therapies". The breakthrough category of drugs accounts for only one-seventh of all new molecular entities approved by the FDA each year. Between 1975 and 1991, The FDA approved annually 22 new molecular entities, about three of which promised major new therapeutic potential. If the Administration's proposed Advisory Council on Breakthrough Drugs would only be responsible for reviewing these drugs that represent major therapeutic advances, the Board would review a small number of cases each year.³²

A breakthrough price review board therefore has slightly different impacts than a board that affects all patented drugs. An example of a firm facing such a regulation is given in Figure 5.17. The firm illustrated in Figure 5.17 manufactures three products (or three different *types* of products): a breakthrough drug denoted as Product A; a patented, non-breakthrough drug, denoted as Product B; and a drug for which the patent has expired, denoted as Product C. The prices charged and quantities sold prior to the establishment of a price review board are shown in the figure.

Suppose that the government establishes a price review board that applies only to breakthrough drugs. These guidelines will only apply to product A. If we assume that the board's guidelines require that the price for product not exceed price P'_A , then the firm will lower its price and increase quantity. The markets for the other drugs will not be affected. If we assume that the firm was selling at the elastic portion of the consumer demand curve, and that the board was not accompanied by an increase in insurance coverage, then the manufacturer's revenues from the sale of product A will decrease.

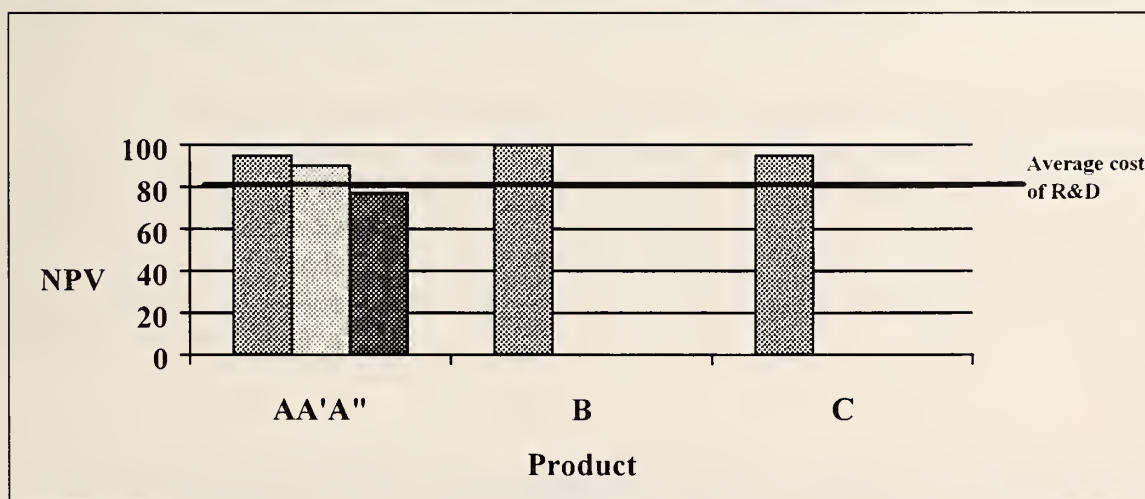
³² Congressional Budget Office (1994), pp. 35.35.

Figure 5.17: Impact of a Breakthrough Drug Price Review Board



In the short run, this policy will result in lower costs of drugs for consumers. In the long run, however, it could shift pharmaceutical R&D away from breakthrough drugs and towards less important products. Suppose, for example, that a manufacturer is considering the development of three potential products shown in Figure 5.18. The vertical bar labeled A represents the manufacturer's best estimate of revenues for breakthrough product A. Bars B and C represent non-breakthrough products B and C. The horizontal line represents the costs of product development.

Figure 5.18: Impact of Price Review Board on Firm R&D Decisions



If a price review board is established that affects only revenues of breakthrough products, then the firm faces potential reductions in the revenue stream only for Product A. One possible scenario is that the expected revenues still exceed expected costs, as shown by the bar A'. In this case, the firm might still continue with the development of product A. However, if the firm has

limited R&D dollars, then it might choose to develop only the products that are expected to be the most profitable--perhaps stopping development of product A. Alternatively, the expected revenue stream may fall below the expected costs to A''. In this case, the firm would be expected to halt production of product A.

It should be clear from this example that the breakthrough price review board can have adverse consequences on the development of breakthrough drugs. It is a clear example of the conflicts facing government policy in drug payment--evaluating lower prices against promoting the development of new drugs and major therapeutic improvements. Particularly in this case, the risks of foregoing drugs offering major therapeutic improvements should be carefully evaluated against the potential gain from cost savings.

Unitary Pricing Laws

A final type of direct government intervention in how prescription drug prices are set involves legislation known as "unitary pricing laws" or "non-discriminatory pricing". Efforts to impose unitary pricing laws reflect a concern that the discounts given to the institutional class of trade represent discrimination on the part of drug manufacturers against the retail class of trade. While the pricing differentials described in the previous chapter represent price discrimination in the economic sense--that is, pricing to different market segments based on each's willingness to pay--this view asserts that the discrimination is unfair in that those who have to pay the higher prices in the retail class of trade are often those least able to pay for it; in particular, low income elderly who have high drug utilization and low ability to pay. In addition, representatives of the retail drug industry, who don't have access to these discounts, claims that this hurts their ability to compete. A number of court cases are in process on whether differential pricing violates federal antitrust laws.³³ In addition, over thirty states have considered the adoption of unitary pricing laws in recent years, and legislation was enacted in Maine in 1995.

It is difficult to predict how unitary pricing laws would affect drug prices. The economic impact of unitary pricing laws is that adoption of laws will probably lower prices in the retail class of trade, but probably not to the level that they are in the institutional class of trade. Rather, prices would probably fall in the retail class of trade and rise in the institutional class of trade. The degree to which each occurs depends on the size of the institutional sector, the power of the institutional sector to obtain discounts, and the degree of competitiveness between products in any particular product line.

³³ Those that argue that differential pricing violates anti-trust laws contend that manufacturers can engage in multi-tiered pricing because they can segment the market according to class of trade (such as retail sales, managed care, hospitals). Market segmentation is possible because the manufacturers have a monopoly in the drug marketplace. Opponents of unitary pricing argue, however, that multi-tiered pricing is actually a result of an increased competitive market rather than a monopoly of the manufacturers. They contend that multi-tiered pricing has resulted because organized buying groups have been able to use efficient purchasing methods and to offer manufacturers value in return for discounts (for example, by shifting sales volume away from competing products). For a discussion of issues relating to unitary pricing, see Schondelmeyer (1994); Berndt (1994); Research Institute of Pharmaceutical Services (1995).

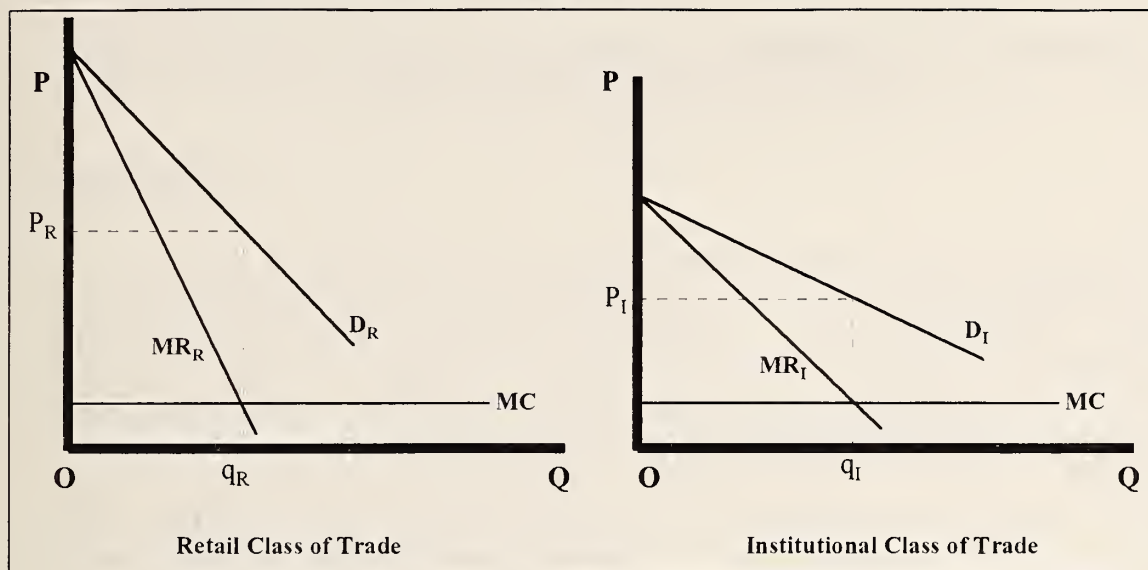
The situation that occurs in the market when unitary pricing laws are implemented is illustrated in Figure 5.19. In Figure 5.19, the drug manufacturer, being a price discriminating monopolist, charges a higher price to the retail class of trade (P_R) than to the institutional class of trade (P_I). The firm has determined that total profits from this differential pricing exceeds the profits that the firm would earn if it priced at a single price P , such that $P_I < P < P_R$.³⁴ But if government regulation requires that the price to the retail sector not exceed the best price to the institutional class of trade, then the firm would likely not lower the retail price to the institutional price--this would result in a lower level of profits than if the firm did not differentiate prices at all.

There is dispute among economists about the extent to which the price would rise to P_R , or whether the retail price would fall to P_I . The actual answer probably depends on the size of the institutional market and the power of that participants in that market to obtain discounts from manufacturers. For example, if the institutional market was a small share of the market, yet received substantial discounts, then manufacturers would face substantial revenue losses by extending discounts to the large retail class of trade. However, for products that can easily be replaced by therapeutically similar medications, the firm may face pressure to give some discounts even though it would require passing that discount to most or all purchasers. As oligopoly theory suggests, it is difficult to maintain high prices in the absence of a cartel--at least one firm may choose to provide discounts. However, given that these discounts would extend to the entire market, it is unlikely that they would be as high as they were prior to the implementation of the unitary pricing laws.

Government regulations on drug prices have the potential to reduce the short run costs to the government of a prescription drug benefit. However, we have seen that each of the four approaches reviewed offers the potential for adverse consequences in the prescription market. They can decrease the operation of competitive forces and bias the incentives for pharmaceutical R&D. In addition, they do not promote efficient use of prescription drugs by patients and providers. However, these policies represent only one set of federal drug payment approaches. The next chapter will examine the effects of drug payment policies that attempt to influence cost sensitivity on the part of patients, providers, and third-party Medicare and Medicaid administrators.

³⁴ It is possible that, for some product lines, the firm cannot act as a price discriminating monopolist, but rather as a firm operating more in a purely competitive framework. This is especially true for generic manufacturers, whose products are not distinguishable from one another on the basis of brand name. It could also theoretically be true for originator drugs that are in very competitive product lines.

Figure 5.19: Impact of Unitary Pricing Laws



CHAPTER 6

IMPACT OF COST SHARING, CONTROLS ON PHYSICIANS, AND USE OF MANAGED PHARMACY BENEFITS

Introduction

Chapter 5 presented the impact of policies that reduce the costs of prescription drugs by regulating the prices that manufacturers can charge. As was discussed in that chapter, some of those policies may be applied to a public drug benefit program. However, rather than using pricing regulations to reduce programs costs and increase market efficiency, the government could adopt reimbursement policies that encourage beneficiaries and their physicians to make more optimal decisions in the use of prescription drugs. These policies make beneficiaries and providers more conscious of the cost of drugs purchased, and give them incentives to reduce utilization or to reduce the average price of the market basket of drugs consumed.

The analysis in this chapter focuses on drug payment policies that can be adopted for the provision of prescription drugs to beneficiaries of Medicare and Medicaid. Prescription drug benefits are optional in the Medicaid program, but every state currently has such a program in place and Medicaid spending accounts for about 16 percent of outpatient prescription drug spending (Levit, et al., 1994). Despite offering generous benefits for hospital and physician care, the Medicare program does not offer a prescription drug benefit. However, the over-65 population currently accounts for about one-third of outpatient drug expenditures, and one health reform scenario could involve providing insurance benefits through Medicare for prescription drug costs. However, there have been a number of attempts to add a prescription drug benefit to Medicare, with most recent attempts being the Medicare Catastrophic Care Act of 1988 (which was repealed in 1989 before taking effect), and the Clinton Administration's proposed Health Security Act.¹

Three types of approaches are examined:

- Cost-Sharing. The first set of policies would increase cost sensitivity by program participants. For example, competing health care reform proposals included different levels of cost sharing for proposed Medicare drug benefits (see Chapter 3). The imposition of deductibles, copayments, and co-insurance all can be used to reduce program costs and to make beneficiaries adopt more efficient drug purchasing practices.

¹ Despite the lack of coverage in Medicare, many of the elderly have prescription drug benefits through other source. It was estimated that in 1991, 54% of all elderly have some form of outpatient prescription drug coverage, with 10% being covered through Medicaid, 37% being covered through employer-sponsored Medigap plans, and the final 7% being covered through individually purchased Medigap insurance (Long, 1994).

- Physician incentives. The second set of policies is directed to physicians, who make the ultimate decision about drug prescribing. In a fee-for-service reimbursement system--particularly one in which the patient bears little or none of the cost of drugs--there is little incentive for physicians to be concerned with prescription drug prices. However, use of policies such as spending targets, physician benchmarking, and prescription drug budgets can be applied to make physicians more sensitive to the costs of competing drugs.
- Managed care. The third set of policies relies on external entities--such as managed care organizations and pharmacy benefits managers--to manage prescription drug benefits for Medicare or Medicaid beneficiaries. These organizations can adopt policies used in the private sector to reduce the costs and improve the cost effectiveness of a prescription drug benefit, in return for a capitated fee for each beneficiary.

The starting point for this analysis will be the impact on the market of creating a Medicare drug benefit that has no cost controls and relies on a fee-for-service reimbursement system. The purpose of this part of the analysis is to show how this benefit expansion affects demand and prices both in the aggregate and for different types of products, and how it affects government costs and returns to drug manufacturers. The remaining sections of the chapter will isolate the impact of the policies described above on reducing the costs of the drug benefit.

Effect of Creating a Medicare Drug Benefit

Even though many of the over-65 population currently have prescription drug coverage, any proposal to extend Medicare drug benefits is likely to have significant impacts on the marketplace. For example, the Congressional Budget Office estimated that the Medicare drug benefit proposed in Health Security Act would increase overall demand for prescription drugs by 4 percent (CBO, 1993). Under this benefit plan, Medicare would pay 80 percent of prescription drug costs after a \$250 deductible has been met. Out-of-pocket payments would be limited to \$1,000 per year. Both the deductible and the out-of-pocket limit are indexed to inflation (Ford, et al., 1994). In addition, consumers would have to make higher copayments if they wanted to buy originator drugs when generic substitutes were available (this copayment would be waived if the physician directed that no generic substitute be dispensed). The impact on demand would be more substantial if a policy were adopted without the cost sharing mechanisms that were part of the Health Security Act.

In order to isolate the impacts of policies such as copayments, we first present an analysis of how the creation of a Medicare drug benefit affects the pharmaceutical market. This analysis can be modified subsequently to examine the impact of cost control policies applied to physicians and consumers. We will not, however, be examining the net impact of the different policies, since the purpose of this analysis is to provide a conceptual

framework for analyzing these impacts rather than to provide a quantitative estimate of the effects of an entire set of policies.

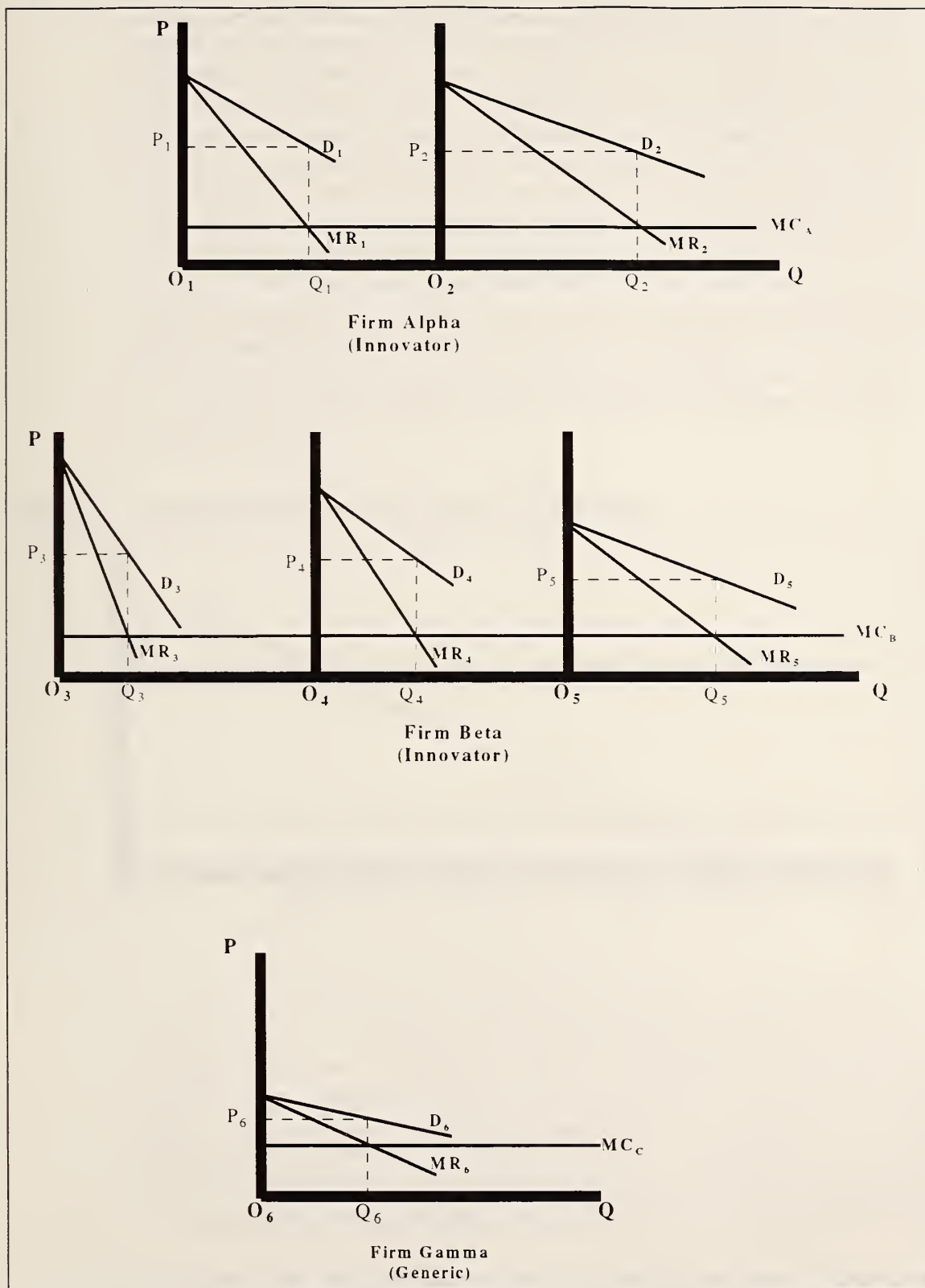
To evaluate the impact of different types of cost sharing arrangements on the pharmaceutical market, a model of hypothetical firms in the pharmaceutical market, based on the conceptual model of the pharmaceutical market developed in Chapter 4, is illustrated in Figure 6.1. For ease of presentation, the industry is assumed to consist of three firms. Two of these firms, Alpha and Beta, are assumed to be innovator drug firms: the third, Gamma, is a generic manufacturer.² Each of these firms has a constant marginal cost curve that, because of the assumptions presented in Chapter 4, is the same for all products. The firms have some degree of market power, so that they face downward sloping demand curves and choose profit maximizing price and quantity based on the intersection of marginal revenue and marginal cost.

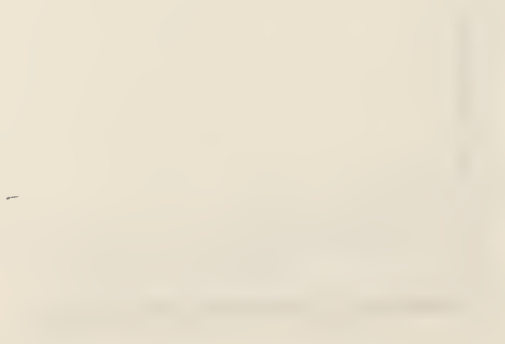
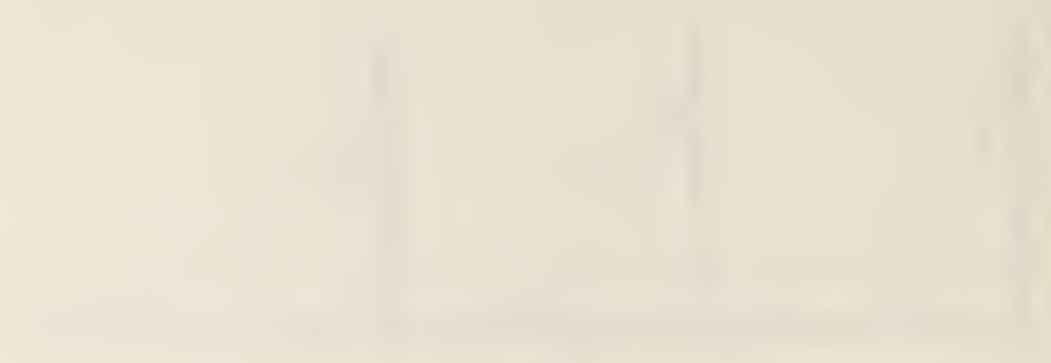
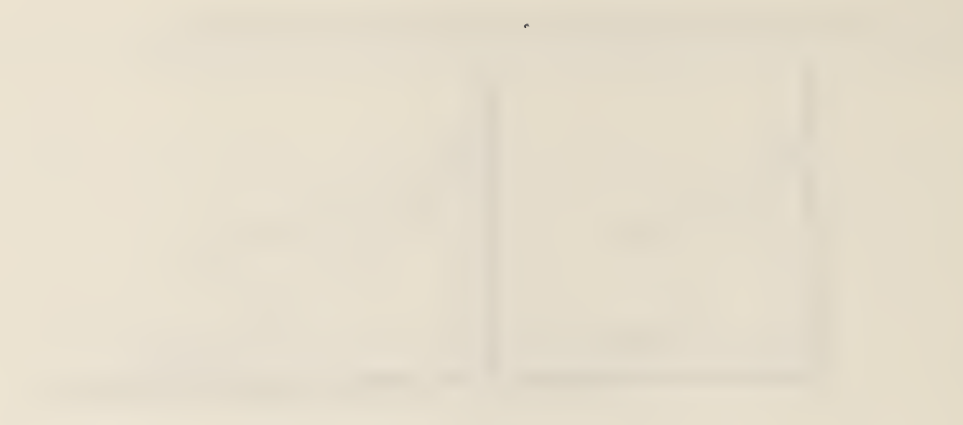
As is shown in the top panel of Figure 6.1, firm Alpha manufactures two products, denoted as products 1 and 2. The demand and marginal revenue curves faced by the firm are as shown, and represent the marketwide demand rather than the demand of an individual consumer. Firm Beta manufactures products 3, 4, and 5. Drug 5 is assumed to be therapeutically similar to firm Alpha's drug 2. While the products are not perfect substitutes for one another (that is, they are not biologically equivalent), they are similar enough that physicians may prescribe either one for a particular treatment. In addition, Beta's drug 3 is assumed to have lost its patent protection. A generic substitute for drug 3, denoted as drug 6, is produced by generic manufacturer Gamma. The relatively steep demand curve for drug 3 represents the lack of price sensitivity on the part of consumers who choose drug 3 instead of generic drug 6.

For the purpose of this presentation, we will assume that most Medicare beneficiaries fill their prescription drug needs at retail pharmacies. They either pay the market price for the drugs, or present a card which the pharmacist uses to charge Medicare directly.

² For ease of exposition, it is assumed that neither Alpha nor Beta manufacture generic versions of drugs. In practice, however, many innovator drug companies do manufacture generic drugs or have generic drug subsidiaries.

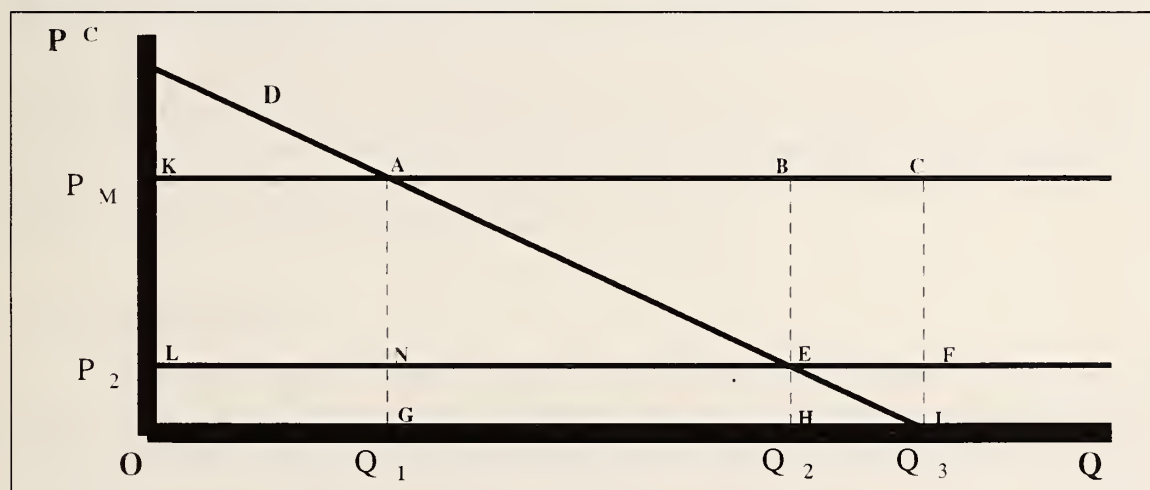
Figure 6.1: Prescription Drug Market with Multi-Product Firms





- The first impact of instituting a Medicare drug benefit will be an increase in demand for all products. This increase will come from: (1) Medicare beneficiaries who previously had no insurance; and (2) induced demand by beneficiaries who had private coverage for prescription drugs but whose consumption had been reduced by the existence of copayments. As shown in Figure 6.2, the increase in insurance will move individuals along their demand curve. Individuals without insurance, for example, would move from Q_1 to Q_3 , where the effective price of prescription drugs is zero. Those with insurance that included cost sharing might move from Q_1 to Q_2 . For the firm, where the vertical axis measures actual price rather than effective price, these changes in quantity demanded by individuals actually imply a shift in demand because the quantity purchased rises while price remains unchanged. This would be reflected by an outward shift in the demand curves for all products. However, as is discussed below, different types of products have different levels of increased demand.

Figure 6.2: Impact of Medicare Prescription Drug Benefit



- The second potential impact of a Medicare drug benefit is on the shape of the demand curves. In particular, fee-for-service reimbursement would be expected to decrease the elasticity of demand for individual products because consumers are no longer sensitive to price. Those consumers who previously sought less expensive therapeutic substitutes in an effort to reduce expenditures no longer have an incentive to do so. Therefore, the curves in Figure 6.1 should become steeper, particularly for products 2 and 3 which are more expensive than therapeutically comparable products 5 and 6, respectively.
- Third, there may be a shift away from the institutional class of trade and toward the retail class of trade. Medicare beneficiaries whose private drug

benefit had previously been managed by PBMs--where demand is more price elastic--might now be in an unmanaged fee-for-service system. Those firms that had been segmenting their markets may find revenues increasing as a result of this shift.

This type of Medicare drug benefit would have various impacts on members of society. For the Medicare beneficiary, it increases consumer welfare to the area OKAJ, corresponding both to increased consumption at an effective price of zero and the reduction in out-of-pocket costs. Whether the quantity of drugs supplied exceeds the "medically necessary" quantity of drugs provided is beyond the scope of this analysis, but is an issue that should be considered in evaluating the policy. In order to provide this increase in consumer welfare, the benefit as designed creates substantial government costs, denoted as area OKJG. Part of this cost, area AJC, is the excess costs that accrue because the government payment for the drugs consumed exceeds the value that consumers place on those drugs (that is, the amount shown by the demand curve).

The increased demand and shift toward more inelastic demand would increase incentives for manufacturers to engage in pharmaceutical R&D. In particular, the guarantee of reimbursement for the elderly might increase the relative importance of drugs that are used predominately by the elderly. However, the incentives don't necessarily point solely to drugs that provide major therapeutic improvements over existing therapies. If the reimbursement policy makes Medicare beneficiaries less sensitive to market forces, then the relative value of imitative ("me-too") products may rise. Manufacturers may return to their practice of charging higher prices on the basis of actual or perceived differences between the innovative and imitative products.

Cost Sharing Policies

Cost sharing would make program beneficiaries more sensitive to the price of drugs they purchase. Cost sharing can reduce the cost of a drug benefit in two ways. First, it shifts some of the costs of the benefit from the insurer to the consumer. Second, it may reduce unnecessary and inefficient consumption by raising the effective price paid by program beneficiaries. This latter effect gives beneficiaries greater incentives to reduce consumption levels and to substitute lower priced drugs for higher priced, therapeutically comparable medicines.

Cost sharing policies can take one of three forms. First, consumers can be required to pay a *deductible* which requires them to incur a fixed level of costs before insurance coverage begins. The Clinton Administration's Health Security Act, for example, included a deductible of \$250 in its proposed Medicare benefit before Medicare would start paying for drugs. Second, consumers may be asked to make a *copayment* of a certain amount per prescription or per purchase. Copayments, which are instituted either in conjunction with or separate from a deductible, can be the same for all drugs, or can be set at different amounts depending on whether the drug is a lower-priced generic version, is on a formulary, or other reasons that the payer may have for encouraging the use of a

particular product. For example, a Medicare benefit could include a \$5 copayment for all drugs, or could have a \$10 co-payment for brand name drugs and a \$2 copayment for generic drugs. By contrast, *co-insurance* requires the beneficiary to pay a percentage (rather than a fixed amount) of the drug cost. Unlike a fixed copayment, the co-insurance payment necessarily varies with differences in drug price.

Impact of Deductibles

The first policy intervention to be considered is the imposition of a deductible. Deductibles increase consumer price sensitivity by requiring beneficiaries to pay 100 percent out-of-pocket payments for initial levels of consumption. For example, a \$500 deductible means that no insurance benefits will be paid until the beneficiary incurs \$500 in prescription drug costs. An obvious purpose for imposing a deductible is to reduce program costs both by shifting costs to the beneficiary and through the reduction in consumption that will occur as demand adjusts to an increase in the effective price. In addition, the use of deductibles can reduce administrative costs of claims processing when there are many small claims and the cost of claims processing is high. Deductibles have some disadvantages from the perspective of designing a prescription drug benefit. In particular, a sufficiently large deductible may create a financial barrier to needed drugs, particularly to low income program beneficiaries. In addition, deductibles are regressive in that they represent a greater burden as a percent of income to low income households than to higher income households (Feldstein, 1994; McMillan and Jenkel, 1993). These effects can be somewhat reduced by exempting lower income beneficiaries from paying the deductible; however, this will limit the effects of the policy at reducing costs and promoting more efficient consumption.

In order to assess the impact of a deductible on individual product demand, assume that Medicare assesses a deductible of \$250 for prescription drugs (this deductible is separate from the deductible applied to other medical services). Prior to the deductible, the Medicare beneficiary is assumed to pay an effective price of zero for all prescription drugs. This situation is represented in a Medicare beneficiary's demand for a particular product, pictured in Figure 6.3. The vertical axis in Figure 6.3 shows effective price to the consumer (denoted as P^c), rather than the market price. When the consumer has 100 percent coverage, quantity demanded will be OE--corresponding to a zero price--regardless of the actual market price of the drug.

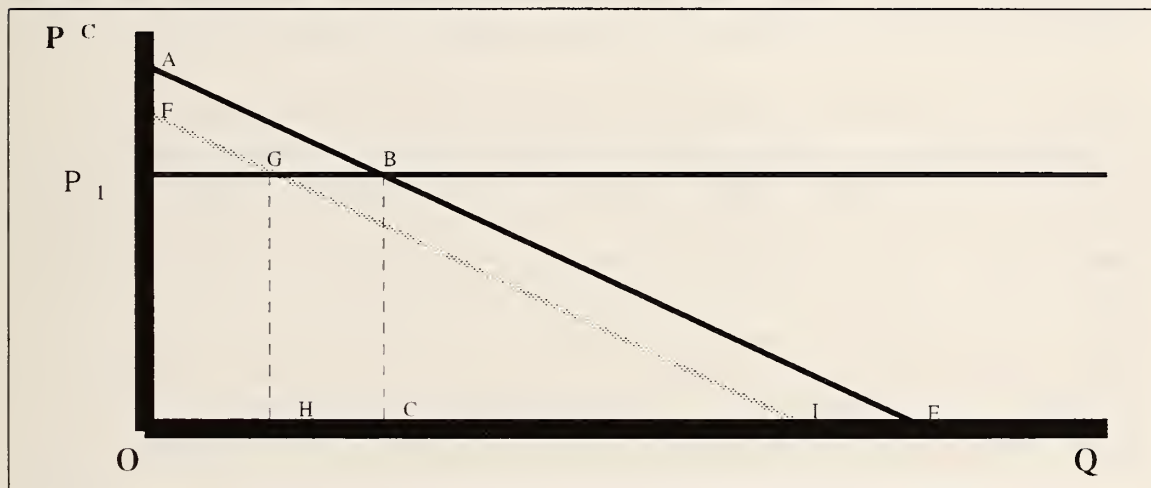
How deductibles affect consumer behavior. In exhibiting the impact of the deductible on an individual's demand for drugs, we will first assume that the individual consumes only the product shown in Figure 6.3. (Alternatively, we could assume that Figure 6.3 represents all drugs consumed; that the vertical axis measures the average price of drugs; and that demand curve represents a ranking of drugs consumed in order of decreasing marginal utility). It is assumed that the demand curves represent a market in which there is both a Medicare and Medicaid drug benefit with no cost sharing.³ The

³ Note that we are not comparing the use of control in a Medicare drug benefit to the current situation, which is no Medicare drug benefit whatsoever. In this example, two separate events are occurring: first,

Medicare benefit is assumed to be a fee-for-service type of benefit, under which consumer prescriptions are filled in retail pharmacies without intervention by managed care organizations or pharmacy benefits managers. Pharmacies and drug manufacturers are free to set the prices that they charge to Medicare beneficiaries for products (although limits may be placed on pharmacy dispensing fees). Consumers are assumed to have 100 percent coverage; no deductibles or other cost sharing are required. Note that the demand is for the entire market, not just for Medicare beneficiaries.⁴

Assume that the market price of the drug is P_1 , and that the value of the deductible is equivalent to the area OP_1BC . This means that the beneficiary must pay the market price P_1 for quantities less than or equal to OC , and that all subsequent purchases will receive 100 percent payment from Medicare.

Figure 6.3: Impact of Deductibles on Demand by Individuals



The impact of the deductible will to some extent depend on the consumer's demand curve relative to the deductible. For the example given above, imposition of a deductible has no impact on the quantity of drugs demanded by the consumer. As shown by the demand curve, the consumer is willing to pay market price P_1 for quantity OC of the drug. Since price falls to zero after this level of consumption, the consumer will be able to obtain quantity OE without increasing expenditures over the deductible. While total drug spending will remain unchanged, the cost to the Medicare program cost is reduced by the amount of the deductible.

the creation of a Medicare drug benefit that should expand demand for drugs; and second, the adoption of a cost control mechanism within that benefit, which should contract demand. By focusing only the second part of this scenario, we are isolating the impact of a Medicare cost control policy from that of a Medicare expansion.

⁴ The linear representation of demand is a simplification of market demand shown for ease of exposition. The actual market demand curve will be kinked, reflecting the effects different levels of different copayments and deductibles for different types of consumers in the market.

Suppose, however, that the consumer's demand was actually represented by the downward sloping line FI. In this case, the beneficiary is only willing to buy OH of drugs at price P_1 . This implies that at price P_1 , the deductible exceeds the amount of prescription drug spending the Medicare beneficiary is willing to make. This beneficiary will adjust to the increased costs through a combination of (1) reducing consumption (that is, moving along the demand curve), and (2) trying to reduce the average price paid for drugs. The reduction in consumption can be accomplished by eliminating both medically unnecessary and necessary usage.

If the consumer relies solely on decreases in consumption to reduce spending, then she will reduce consumption by quantity HE, and will incur no costs for the Medicare system.. Medicare drug costs fall to zero, as do the social welfare costs of providing this particular product (or set of products) to this individual. However, the deductible could restrict consumer access to drugs, if the beneficiary's "needed" quantity of drugs exceeds OH, the reduced level of treatment may result in increased illness, more medical costs, and lost productivity. In this case, the welfare loss may exceed the cost of the drugs foregone.

Alternatively, the consumer could reduce spending by decreasing the average price of drugs in this consumption bundle. Reducing average price paid can be accomplished by using more generic substitutes and--to the extent possible--seeking other lower-priced therapeutic substitutes (including over-the-counter medicines). The extent to which this substitution occurs will depend on the availability of substitutes (e.g., whether generic drug or other therapeutic substitutes exist), the consumer's knowledge of the availability of substitutes, and his willingness to use generic drugs when such products exist. Even if the consumer is willing and able to reduce the price paid for drugs (or the average market basket price), the government still will not entail costs for this beneficiary--the consumer's budget constraint, which originally restricted her from reaching the deductible, has not changed.

In practice, those beneficiaries who are likely to reduce consumption would include people with relatively low incomes (but not sufficiently low as to make them eligible for Medicaid, which has no deductibles) and those whose total drug costs are low relative to the deductible. Those beneficiaries whose drug spending is high relative to the deductible may be willing to spend the deductible quickly because they know that their subsequent consumption will be free. Those who adjust consumption are likely to be those with relatively less income and people who do not expect consumption to be far above the deductible.

Limited impact of deductibles. While the deductible increases cost-consciousness of consumers relative to no cost sharing, its effect is limited because it provides no incentives for efficient behavior once the deductible is met. Those beneficiaries with relatively high rates of utilization--those most likely to exceed the deductible--have no incentive to seek lower priced drugs or to reduce utilization that may not be medically necessary. Furthermore, the levels of consumption affected by the deductible are those that contribute the highest levels of utility. If the demand for prescription drugs does,

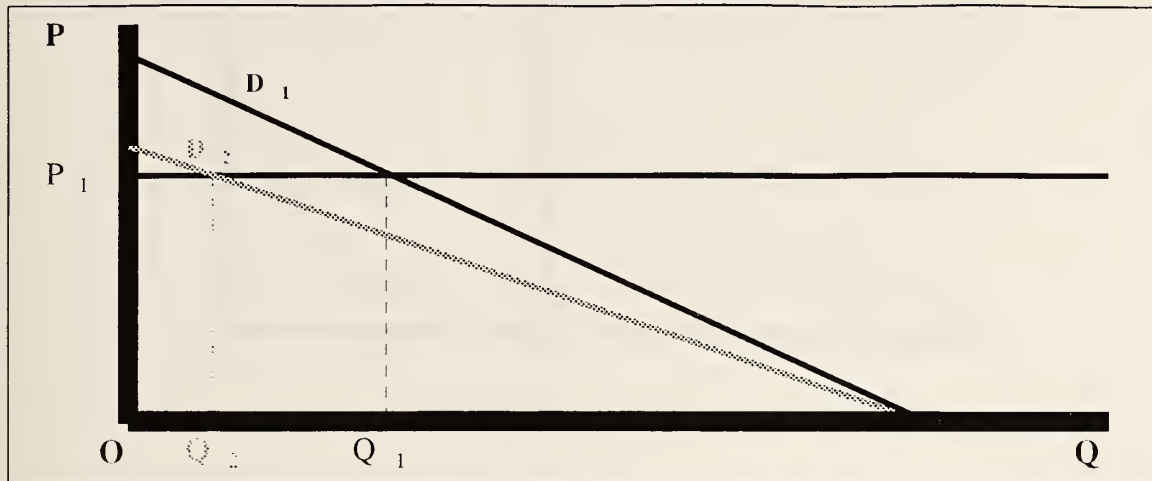
indeed, represent a ranking of products in order of marginal utility, then consumption of products with relatively lower marginal utility is unaffected by the deductible (McMillan and Jenkel, 1993). This effect runs counter to public policy goals, since the consumption that should be reduced is that which is the least medically necessary.

Market impact of deductibles. Figure 6.3 showed the impact of deductibles as reducing an individual's quantity demanded for a particular product. The marketwide impact is more accurately shown as a shift in demand. Furthermore, as is illustrated below, this impact will vary for different types of products, depending on the level of substitutes available.

The impact of deductibles on drug manufacturers differs from that on consumers. Figure 6.3 showed the impact of a change in the *effective price facing the consumer* as a movement along the consumer's demand curve. For the firm selling to many consumers, however, a higher deductible is equivalent to a shift in the market demand curve. This is because the increase in the deductible, which changes the effective price to the consumer but not the actual market price, leads to changes in consumption without changes in price. As shown in Figure 6.4, the demand curve D_2 represents a change in quantity demanded at every price charged by the manufacturer. If the manufacturer is charging P_1 , then an increase in the deductible results in a movement to demand curve D_2 , and the level of consumption falls to Q_2 (Feldstein, 1994). This shift will likely be greater at lower quantities than at higher quantities, since at higher quantities more consumers will have met the deductible and will not reduce consumption.

The magnitude and direction of these shifts in demand will vary by type of product. For example, there may be a relative smaller shift for products which have few therapeutic substitutes and which are relatively important for health. Consumer willingness to pay would be expected to be greater for products which are necessary for functioning and for which they cannot substitute in reaction to increases in the effective price. By contrast, the decreases in demand will be greater for drugs with substitutes and drugs that are relatively highly priced. The demand for lower priced drugs--particularly generic drugs--may have countervailing effects. On the one hand, the demand would be expected to fall because of the increase in effective price. Alternatively, there may be a substitution effect as consumption shifts from more highly priced drugs to lower priced generic drugs.

Figure 6.4: Impact of a Deductible on Aggregate Demand



Potential impacts of a deductible on the drugs in our hypothetical market are illustrated in Figure 6.5. Demand shifts are relatively small for products with few substitutes, such as products 1 and 4. There is a substantial decrease in demand for product 2, which is more expensive than therapeutically similar product 5, and for drug 3, which has a generic substitute. The demands for drugs 5 and 6 are actually shown to have increased (although this need not be the case).

For illustrative purposes, the magnitude of these shifts has been shown to be significant. In reality, however, it is difficult to predict the magnitude without more detailed product-by-product analysis. It is fair to assume that deductibles would reduce consumption to some extent. As reported in Chapter 3's literature review, cost sharing has been shown to affect pharmaceutical consumption both among low income Medicaid populations and some managed care enrollees (who, presumably, have higher incomes than do Medicaid beneficiaries). If the policy is limited to Medicare beneficiaries, then the impact would be greater on drugs that are used relatively more by the elderly (for example, drugs in the treatment of osteoporosis, heart disease, and Alzheimer's Disease). But because those consumers with high drug utilization might not change consumption substantially, the marketwide impact on total firm revenues and on demand may be small. In addition, any reduction in demand is likely to be lower than the increase in demand associated with the original expansion of the Medicare drug benefit.

Because of the difficulty in evaluating the impact of a deductible on market demand, it is difficult to assess its impact on incentives for pharmaceutical R&D. At worst, a deductible would restrict demand to pre-benefit levels of utilization, so that incentives for pharmaceutical R&D would be no worse than they are now. To the extent that the deductible induces competition among drugs with many substitutes--an effect that is likely limited since all costs are assumed to be covered once the deductible is met--the

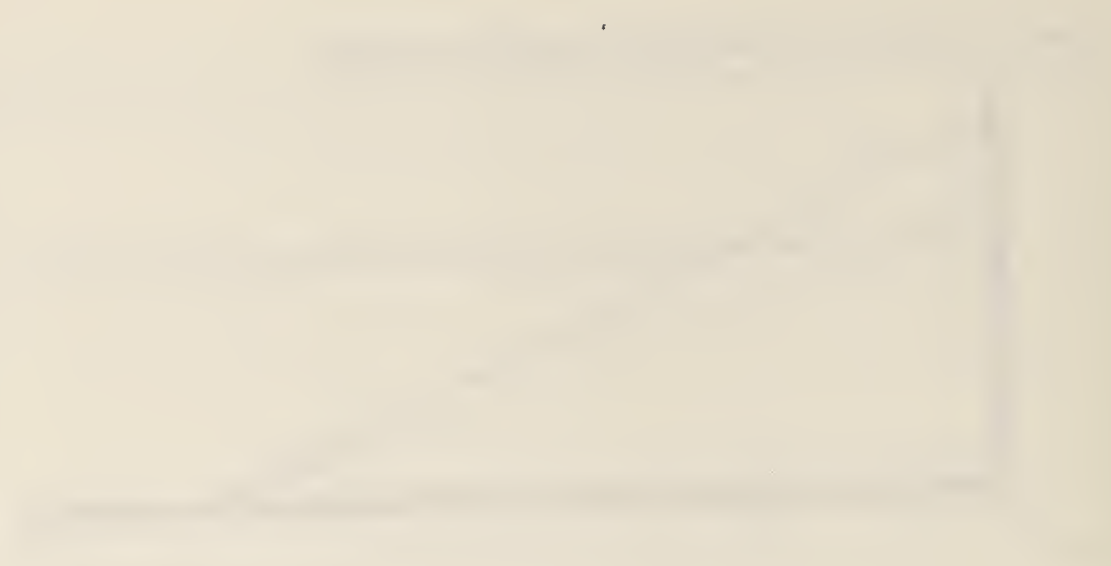
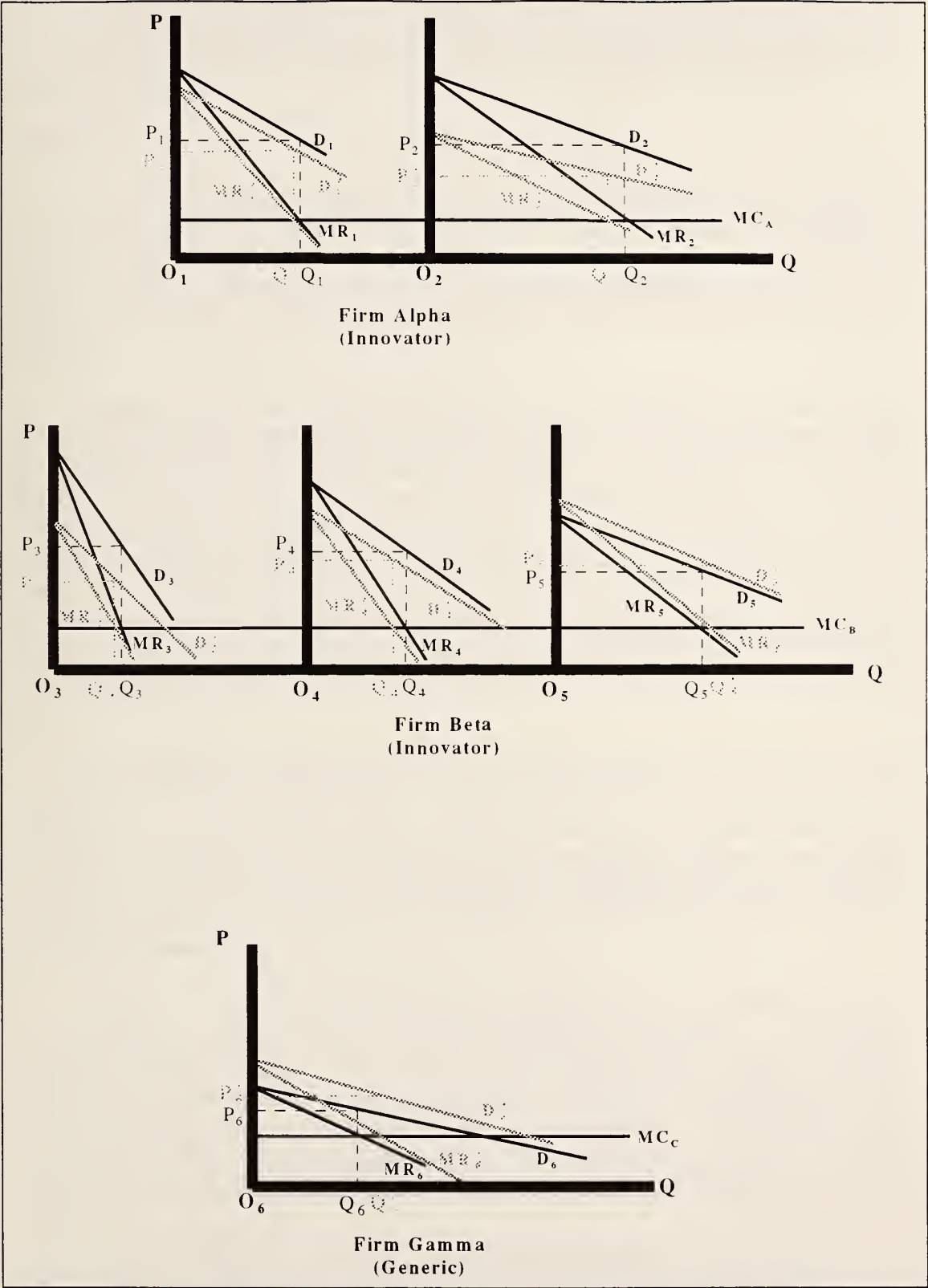


Figure 6.5: Impact of Deductibles on Different Products



expected market value of drugs with many substitutes falls relative to the value of drugs with few substitutes. This may lead to a slight favoring of more innovative products over those with many substitutes. (In addition, it may lead to a slight increase in incentives for generic drug entry.)

Copayments

Copayments represent a second type of cost sharing arrangement that can be used to increase consumer sensitivity to drug costs in a Medicare or Medicaid drug benefit. A copayment requires the beneficiary to pay a fixed amount for each prescription filled. This copayment could be the same for all drugs (e.g., \$2 per prescription), or could vary with different products (for example, a lower copayment for generic drugs or for drugs on a formulary).

Because copayments raise the effective price to beneficiaries, introduction of a copayment will lead to a reduction in individual consumers' quantity demanded for drugs and, therefore, a downward shift in aggregate demand. The magnitude of this shift will depend on the size of the copayment and on consumer elasticity of demand. As discussed in Chapter 3, studies of imposing copayments have shown that copayments as low as 50 cents per prescription can reduce consumption levels, at least for some populations.⁵ The impact will be higher for drugs that have less expensive substitutes available. For these less expensive products, there may be a secondary effect of an increase in demand, due to consumer substitution of less expensive drugs for more expensive products. This would be especially true for generic substitutes, to the extent that consumers do not have a bias against generic drugs.

The magnitude of these impacts will vary from the impacts of deductibles in two important ways. For products that would have been paid out-of-pocket under a deductible, the copayment may have a smaller impact on utilization than does the deductible. This is because the copayment is often--although not always--a smaller share of total price.⁶ However, the copayment will affect consumption on *all* drugs consumed, while the deductible has no impact on consumption levels of drugs purchased after the deductible has been met.

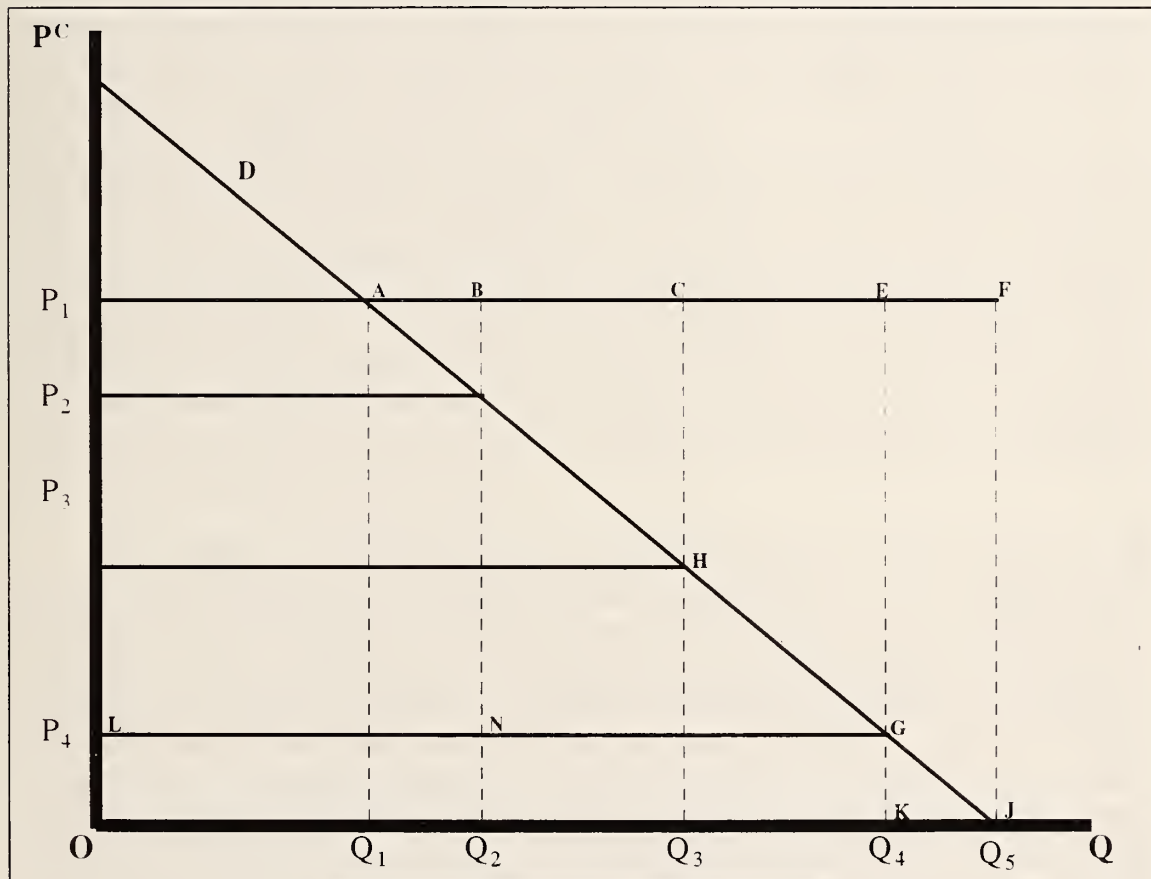
Figure 6.6 shows the impact of imposing a fixed dollar copayment that does not vary by product on demand by a hypothetical Medicare beneficiary. Assuming the existence of a Medicare drug benefit without any cost sharing, the beneficiary consumes quantity Q_5 of the product, or a consumption level of OJ ; cost to the consumer is zero. However, if a copayment of OL is imposed on each prescription, then the effective price to the consumer rises to P_4 for each prescription. The immediate impact for this consumer would be to move up the demand curve, to a quantity demanded equivalent to OK . So

⁵ See, for example, Nelson, et. al. (1984); Reeder and Nelson (1985); Soumerai, et. al. (1987).

⁶ When the drug price is less than or equal to the co-payment, the impact is identical to that of a deductible when the deductible has not yet been met.

long as the “necessary” level of consumption is less than or equal to Q_4 , then this shift increases market efficiency and does not adversely affect consumer health. Government expenditures will fall by area $EFJK$ (due to the reduced consumption) plus area $OLGK$ (due to cost shifting from Medicare to the consumer). Excess government costs fall by $EFJG$, and consumer surplus will fall by GJK . If, however, the necessary level of consumption is between Q_4 and Q_5 , then the patient will be unable or unwilling to purchase the necessary quantity of drugs. Health may be adversely affected, and the patient may eventually seek more costly medical care or be less productive in outside activities. This would result in an inefficiency that is not captured in the examination of this particular market.

Figure 6.6: Impact of a Fixed Dollar Copayment on Demand by Individuals



In addition, the consumer may further reduce expenditures on this product (or this set of products) by changing the mix of products consumed to less expensive products. If this drug is relatively expensive, the existence of the copayment makes the consumer sensitive to a price to which he was not sensitive when the effective price was zero. If a less expensive drug is available, and if units costs of the drug are less than P_4 , then the consumer has an incentive to purchase that product, and will do so if the cost difference outweighs any perceived disadvantages of the lower priced drug. (For example, if the product is a generic substitute, the price difference must be sufficient to counter any



aversions to generic drugs that the consumer may have). But if the lower priced drug also has a copayment of OL--that is, if price is equal to or exceeds P_4 , then the beneficiary has no incentive to choose the lower priced product.

The example noted above presents one serious limitation of copayments. While copayments have the advantage of shifting cost from the government to the beneficiary, they do not necessarily encourage consumers to change the mix of products to relatively less expensive, equally effective drugs. Indeed, when all products have the same copayment, consumers have an incentive to choose the more expensive product if they feel that higher prices represent better quality.

This effect can be reduced by instituting a system of differential copayments. For example, a government program could follow the procedures used by some MCOs and pharmacy benefits managers by setting lower copayments for generic drugs than for branded products. Another example is to create a drug formulary, and to have lower copayments on formulary drugs than for products not on the formulary. In this way, consumers have a financial incentive to choose products which are less costly or are otherwise deemed to be more cost effective. Germany's reference price system offers another example of differential copayments. Under this system, drugs are put into categories based on bioequivalency (that is, being generic substitutes for one another) or being therapeutically similar to one another. A reimbursement rate is determined that is roughly the average price for each category; this rate is known as the reference price. The health insurance reimbursement for each product is restricted to the reference price. Consumers buying drugs priced above the reference price must also pay the difference between that price and the reference price (in addition, they must make a small copayment regardless of the drug's reference price).

The impacts of copayments on the prescription drug market--and on pharmaceutical manufacturers--depends on their magnitude and on the willingness of consumers to absorb copayments. In all likelihood, there would be some downward shift in aggregate demand, similar to that shown for deductibles in Figure 6.4 (though not necessarily of the same magnitude). The degree of substitution depends on the extent to which copayments exceed the prices of lower cost drug, although the impacts would be greater under a differential copayment system than under a system that uses a fixed copayment. In Germany, for example, where consumers historically have been exempt from making copayments (as late as 1993, some drugs required no cost sharing), the institution of reference prices led to a reduction of almost all prices to the reference price (GAO, 1994a). Americans, who are more used to making copayments, may be more willing to make some copayment for certain products.

As with deductibles, copayments suffer from a shortcoming in that there is no relationship between the amount that beneficiaries must pay and the cost effectiveness of a particular drug. Consumers may pay less for a product that has a lower price but that is less effective than its substitutes. This may be especially true when consumers are choosing between a generic product and a more recently developed patented drug that

may be more effective (for example, the newer drug may have a greater probability of success, or have lower incidence of side effects). There is no relationship between consumer cost savings obtained by choosing a less expensive drug and cost savings to the health care system that may be obtained from use of higher priced products.

Co-insurance

A third means of cost sharing is the institution of co-insurance. Co-insurance differs from copayments in that the cost sharing is a percentage of the drug's price. For example, co-insurance may require consumers to pay 20 percent of the cost of a drug, with the insurer paying the rest. The use of co-insurance is intended to increase cost sensitivity by requiring consumers to pay some of the costs while maintaining much of the benefit of insurance coverage.

As with other types of cost sharing, co-insurance will cause a downward shift in the quantity demanded by individual consumers by raising the effective price of drugs. The magnitude of the impact will vary for different products. For example, the impact will be greater for higher cost products, *ceteris paribus*, because the out-of-pocket payment is greater in absolute terms. The impact will also be greater for consumers who have relatively high levels of utilization. Institution of co-insurance can be expected to reduce the quantity demanded for drugs and, more than copayments, increase the consumer incentives to change the mix of drug purchases toward lower priced drugs (although the size of that incentive will depend on the price spread between any two products). These impacts on individual consumers will result in shifts of the demand curves facing firms.

A cost sharing requirement under a Medicare drug benefit would have a significant impact on drugs used largely by the elderly population, since almost the entire over-65 population would be covered under the benefit assumed in this illustration. For example, suppose that products 3 and 6 in Figure 6.5 were mostly used by the elderly. While Medicare beneficiaries can be assumed to use all the drugs in the illustration, they dominate the market for products 3 and 6. While the co-insurance might affect, say, 20 percent of the market of product 1, it might affect 90 percent of the market for products 3 and 6. Therefore, the relative demand response would be much greater for drugs 3 and 6 than for drug 1. In addition, generic drug 6 may experience a secondary effect of increases in demand if the higher effective price led users of drug 3 to switch consumption to product 6. The magnitude of the shift would depend on the price difference and on consumer willingness to buy generic drugs.

Market wide impacts. Unlike deductibles and copayments, cost sharing provides an incentive for consumers to buy lower priced drugs for all levels of consumption. Therefore, while cost sharing in a government drug benefit shifts some of the costs from the government to beneficiaries, it also reduces consumption. Drug manufacturers would likely see a drop in revenues, particularly for relatively high cost products that have less expensive therapeutic substitutes. However, whether the decreased revenues would have an adverse affect on pharmaceutical research and development--particularly given that the

decrease would likely be less than the increase associated with the adoption of a Medicare drug benefit--is difficult to determine.

Drug manufacturers could adopt a number of responses to cost sharing (relative to what they would do under a Medicare benefit with no cost sharing). For some products--particularly those with a large share of sales to Medicare and less expensive therapeutic substitutes, they may decide to lower prices to better compete in the marketplace. The extent to which they do so depends on the size of the market that can be maintained in the face of price competition. A manufacturer that is able to differentiate its products to a large enough segment of the population may find it less profitable to lower price than to maintain a small niche of price inelastic consumers. In the long run, firms may find it advantageous to adopt a strategy of increasing demand for their products through marketing that sets up competition on actual or perceived quality, rather than on price. Another strategy would be to develop similar products that have slight differences (e.g., less frequent dosing requirements) that set a product apart from competitors.

Impacts on access to care. As with other forms of cost sharing, co-insurance may also create financial barriers to some consumers. While these barriers may not be as substantial as deductibles (at least at lower quantities of consumption), they are expected to reduce consumption levels. For some lower income beneficiaries, this reduction may be below the level of drugs that are medically necessary. This creates not only problems of equity, but also could lead to higher costs if the reduced consumption creates further medical problems.

Controls on Physicians

A second set of approaches for reducing the costs of a government prescription drug benefit is to increase incentives for physicians to practice prudent and cost effective (or cost minimizing) prescribing. This type of policy recognizes the considerable role played by physicians in determining the drug that will be dispensed. Since it is the physician's knowledge about drugs and drug treatment that typically determines what products will be prescribed, emphasizing the physician's role has been a policy used in both private and public sector programs.

A number of approaches can be used to encourage price sensitivity on the part of the physician. One relatively simple approach is to require the physician to denote on a prescription whether a generic should *not* be prescribed. This type of approach proactively promotes the use of less expensive generic substitutes, limiting the use of unpatented originator drugs to those cases where the physician specifically requires it. Other approaches are more complex and some would create financial incentives for the physician to consider differences in costs. These include:

- Educational information. In the United Kingdom, physicians receive information from the National Health Service about the relative efficacy of certain products (GAO, 1994a). While this information is not all encompassing

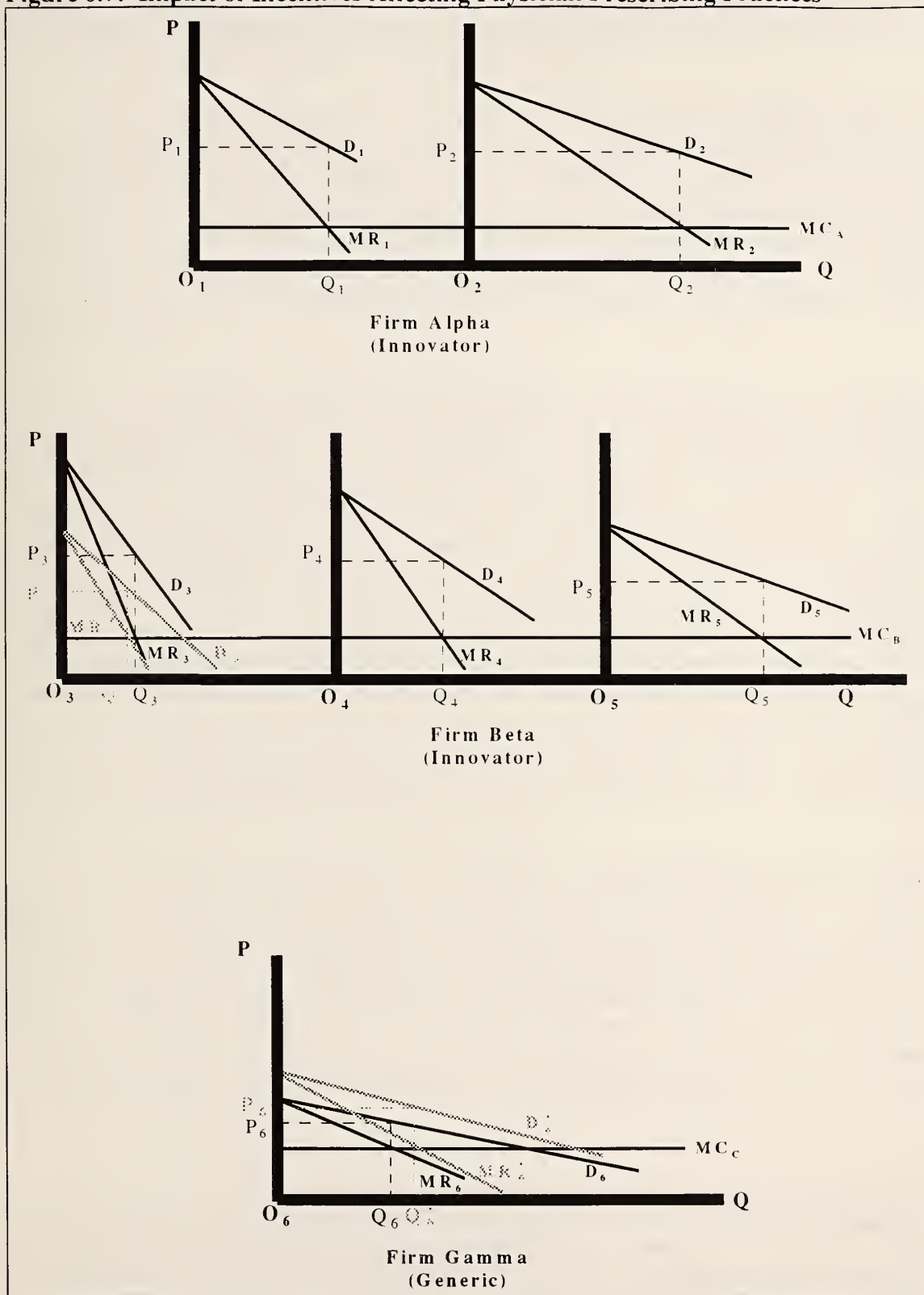
and is not provided for all drugs, it gives physicians objective information about the relative costs and efficacy of alternative products. Similar information is given by some managed care organizations in the United States.

- Physician benchmarking. Also in the United Kingdom, physicians are given periodic reports on the number and cost of the drugs they prescribed, compared to norms for similar physicians in their geographic area. This information is intended to allow the physicians to make more responsible choices about prescribing (GAO, 1994a). Again, similar approaches are used by some American managed care organizations.
- Prescription drug budgets. A more rigorous type of constraint is a budget on total prescription drug spending. In Germany, physicians are subject to a budget on outpatient prescription drug spending as well as a budget for outpatient physician services. To the extent that spending exceeds the budget, the physician services budget is reduced. Since being implemented in 1993, prescription drug spending in Germany has been maintained within budgeted levels (GAO, 1994a; 1994c)

These types of policies can affect prescription drug spending in two ways. First, they may lead physicians to reduce prescribing of drugs that are not medically necessary. This trend is especially true in European social insurance systems, where low costs to patients have contributed to levels of drug consumption that are high relative to U.S. standards (OECD, 1995). Second, they may encourage physicians to change the mix of drugs that they prescribe to products that are less costly, including both generic drugs and lower-cost patented products.

The potential impact of these policies on firms is shown in Figure 6.7. Figure 6.7 illustrates the changes in the market for two drugs sold in this marketplace--drug 3 and its generic competitor drug 6. If physicians are given financial incentives or requirements to use less costly drugs, then demand will shift from the more expensive drug 3 to the less expensive drug 6. In addition, demand for drug 3 may become more price elastic, given increased market sensitivity to price. This would be particularly true if the program being affected constitutes a dominant share of the market for drug 3. By contrast, there may not be similar shifts between drugs 2 and 5, which as shown are already similar in price.

Figure 6.7: Impact of Incentives Affecting Physician Prescribing Practices



Demand may become somewhat more price elastic--reflecting a greater willingness to buy less expensive substitutes when they exist--but there would be little financial incentive to shift from one product to another similarly priced product.

The marketwide impacts will obviously vary by the size of the market segment to which the policy is being applied. For the Medicare market, the effect will be quite substantial, since Medicare beneficiaries could be expected to account for over one-third of the market. For the Medicaid market, it will be much smaller, but likely still significant. However, the results will be much greater if physicians adopt these spending control approaches to other patients as well, since physicians who must adopt cost saving practices from one large group of patients could be expected to adopt similar practices for all their patients.

The magnitude of these impacts will depend on the rigor with which they are applied. Clearly, the most effective type of approach will be one that penalizes physicians for overspending a budget. In Germany, tight controls that would reduce physician reimbursement if drug spending exceeded the budget contributed to a 20 percent reduction in pharmaceutical expenditures in the first year that the policy was in effect. While German government officials attribute some of the reduction to the cost sharing and price reductions, they attribute about two-thirds of the savings to a decrease in the number of prescriptions; an increase in the prescribing of therapeutically similar, but less expensive medicines; and a reduction in certain categories of prescriptions that are of questionable value. Despite concerns that the budget would decrease access to important drugs, government statistics show that the bulk of the reductions have been applied to these therapeutically questionable drugs (GAO, 1994c).⁷ Furthermore, there has been a shift from newer medicines toward older, more established medicines as well as a movement toward lower-priced generic substitutes (Münnich and Sullivan, 1994).⁸ Other policies may be effective, but their impact is difficult to predict.

The impacts on patient access to drugs and on total government costs of a drug benefit with physician controls depends on which drugs are substituted for one another. The same potentially adverse effects can occur under this type of policy as can occur with consumer cost sharing, in that the lower priced drugs may not be the most cost effective drugs. Programs that target total prescription drug spending neglect the possibility that higher priced prescription drugs could reduce other health care costs. By giving physicians incentives or requirements to choose the least costly drug, the regulations may not be promoting the most effective drug and could potentially be promoting a policy that increases total program costs.

⁷ Among these drugs are products for treating low blood pressure, vitamins (other than those for pregnant women or people with osteoporosis), mineral preparations, and cholesterol reducing drugs that were prescribed before other measures, such as changing dietary habits, were taken.

⁸ A drug budget's impact on utilization is likely to depend on utilization patterns prior to imposition of the budget. Germany's experience is consistent with a perception of high drug utilization in Germany, especially for drugs of questionable therapeutic value. In a system with a lower level of drug utilization, implementation of drug budgets could reduce access to medically necessary drugs.

External Management of Pharmacy Benefits

The use of controls on consumer payments and on physicians reflects a prescription drug benefit that is both financed and administered by a government entity. An alternative approach to providing this benefit is to do so through outside entities, such as managed care organizations or pharmacy benefits managers, which receive capitated payments for providing pharmacy benefits. These organizations have extensive experience as providing drug benefits to the private sector and, to a limited extent, to Medicare and Medicaid beneficiaries. In an MCO, the drug benefit is provided as part of the total health care package offered to enrollees. This approach could be used if Medicaid or Medicare beneficiaries were required or given expanded options to choose managed care for their benefits; an element of the capitated payment would cover the cost of pharmacy benefits. A PBM, which often provides stand alone benefits to private insurers (as well as administering pharmacy benefits for some MCOs), could be used to administer pharmaceutical benefits for Medicare and Medicaid beneficiaries under the current non-managed element of the Medicare and Medicaid programs. The PBM would receive a capitated payment only for the cost of prescription drugs.

By paying a PBM or MCO to provide prescription drug benefits, the government shifts the financial risk and responsibility for cost control to outside entities. Assuming that beneficiaries have a choice from among several MCOs or PBMs, this can promote the operation of competitive forces in the provision of the drug benefit and increase efficient utilization of drugs in the following ways:

- MCOs and PBMs, which would receive a capitated payment from the government, will have an incentive to find the least costly (or most cost effective) way of providing drugs to beneficiaries, encouraging the use of less expensive products where appropriate. Organizations that administer an expensive prescription drug benefit may find that the government payment is not sufficient or, if they are allowed to charge supplemental premiums to beneficiaries, that beneficiaries will opt for lower-priced payers. PBMs and MCOs that try to cut costs by reducing access to drugs may find that patients choose more amenable organizations, or that patients who lack access to drugs may be incurring additional medical costs because they did not receive sufficient drug treatment.
- Presumably, quality and access to necessary drugs would be assured by a combination of consumer choice of drug provider, physician participation in prescribing decisions, and oversight by government and independent quality assessment boards. Cost savings could be achieved if the government adopted a program whereby PBMs and MCOs bid to provide services to Medicare or Medicaid beneficiaries; this bidding give an incentive to charge the lowest possible price to the government.

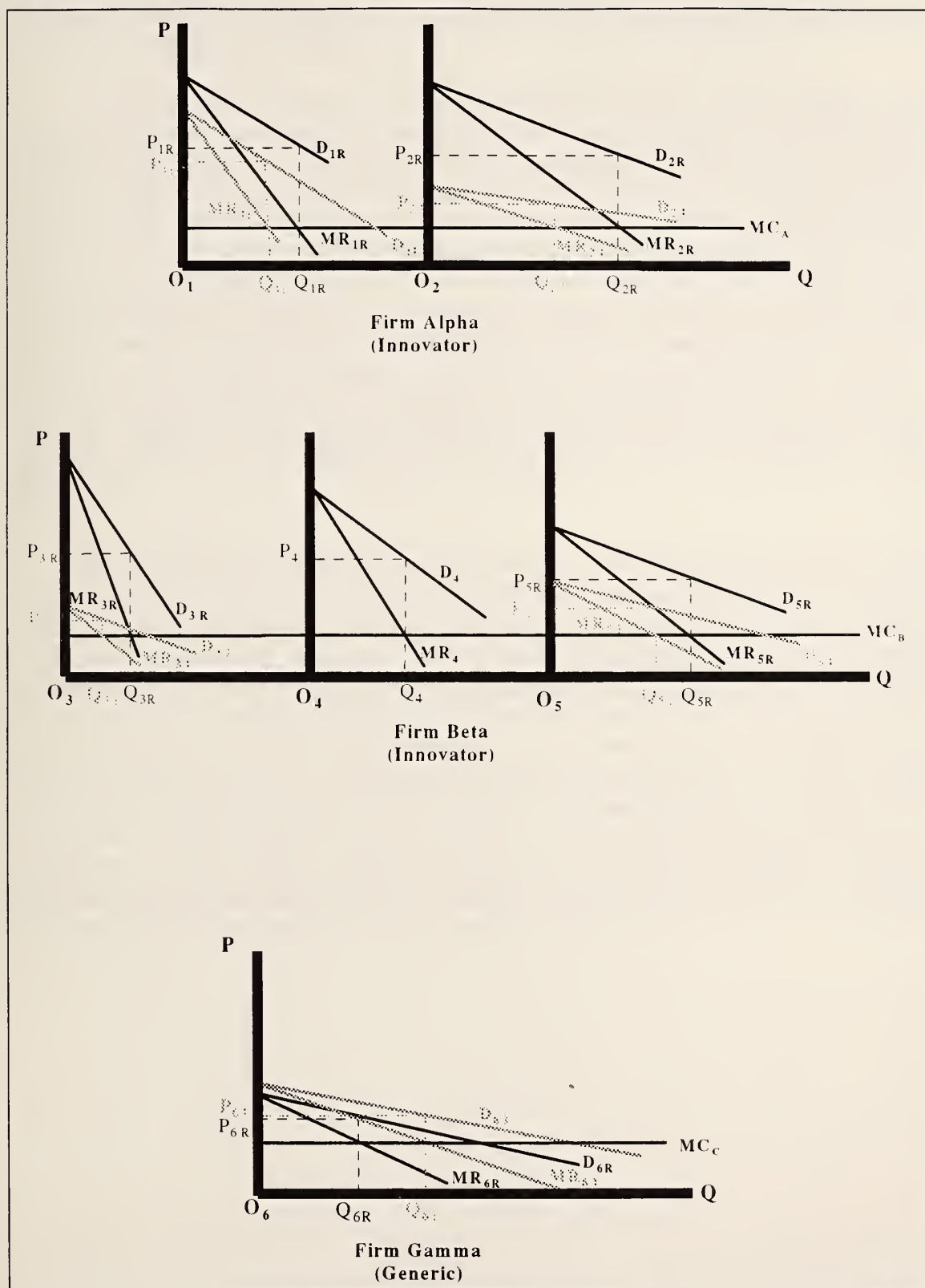
When a pharmacy benefit is administered by a managed care pharmacy organization (that is, an MCO or a PBM), the organization chooses an approach or set of approaches best suited for it to reduce costs. Among the policies frequently used are compulsory generic substitution, use of mail order pharmacies, patient cost sharing, and physician benchmarking or education on alternative drug costs and efficacy. In addition, these organizations are able to negotiate price discounts or rebates from manufacturers and engage in innovative payment arrangements with drug manufacturers. Approaches in the latter category include capitation of therapeutic categories--under which the manufacturer agrees to provide all treatment for a certain cost.

The effect on the pharmaceutical manufacturer of using managed pharmacy benefits should be lower revenues than those obtained under a fee-for-service approach. To illustrate this, assume that Figure 6.1 shows only the retail class of trade, and that for each drug there is an institutional class of trade for which demand is relatively more elastic than in the retail class. In markets where substitutes exist, the demand curve in institutional class of trade is flatter (reflecting the ability of buyers in that class to leverage discounts from competing manufacturers). In Figure 6.8, this effect is shown for competing products 2 and 5; and competing products 3 and 6. In addition, managed pharmacy organizations may have a reduced demand for products without therapeutic substitutes, as shown by the market for product 1. This reflects more prudent purchasing practices and assumption of a greater level of drug utilization review for highly priced products. (For simplicity, we are assuming that the institutional class of trade is not differentiated from the retail class for product 4.)

Assume that the Medicare drug benefit displayed in Figure 6.8 is now administered by pharmacy benefits managers. This means that all prescription drugs received by Medicare beneficiaries are now being provided in the more competitive, lower-priced institutional market. There will be downward shifts in the demand for the retail class of trade, and outward shifts in demand for the institutional class of trade. These shifts can result in significantly lower prices charged by manufacturers for drugs used by program beneficiaries. The institutional price will likely be lower for all products than is the retail prices. As a result, overall revenues for drug manufacturers should decrease. However, revenues may increase for particular manufacturers who sell lower-priced products. For example, a substantial amount of demand should shift to the generic drug 6; product share should also shift to the either product 2 or product 5, depending on which is less expensive.

The use of competitive forces will have an impact on the relative returns of innovative vs. imitative products developed in the R&D process. The use of managed pharmacy benefits will yield lower prices to drugs that face market competition, but fewer price reductions for drugs with fewer competitors or that have more therapeutic importance. This means that the return to "me-too" drugs--products that are similar to existing product lines--are reduced. Competitive pressures will give the highest returns to products that offer unique characteristics, therefore driving pharmaceutical manufacturers to focus on such products in their development efforts. In addition, it should promote

Figure 6.8: Impact of Managed Care Benefits



competitive forces over the long run as manufacturers try to enter profitable product lines that face few therapeutic substitutes.

An additional advantage of managed pharmacy benefits is that managed care organizations have incentives to use drugs in a cost effective manner. In this way, this approach differs from other drug payment policies examined. The search for cost effective treatments reflects the incentives in managed care organizations to be concerned with the lowest cost way of achieving a certain medical outcome. MCOs, which are able to control all aspects of utilization for which they pay, are able to absorb high costs for drugs that may reduce other health care costs or achieve better outcomes. By contrast, other payment mechanisms examined do not reward the patient or provider for choosing more expensive but cost saving drugs. For example, under a cost sharing regime, consumers must pay more to obtain these drugs (while more expensive hospital or physician services may have a lower effective price, depending on the nature of the insurance coverage). Physician budgets or benchmarking target the physician who uses high cost drugs regardless of their impact. Price controls reduce drug prices without regard to cost-effectiveness.

A disadvantage of managed pharmacy benefits is that it may restrict patient access to drugs which the patient may desire or need, but which may not be on a list of preferred medicines used by the pharmacy manager. Unlike in fee-for-service, where the patient and the physician alone decide what drugs will be prescribed and dispensed, an MCO or PBM can restrict patient choice or charge more for products that are not favored by the payer. For example, many MCOs and PBMs have drug formularies that recommend certain products or restrict reimbursement for products. These decisions may be made more on the basis of costs than on cost effectiveness, thereby limiting patient access to the most cost effective drugs. Similarly, the MCO or PBM may have restrictions on how often a prescription may be filled, on the type of product (i.e., regular versus extended release), or on the use of newer products versus older drugs that have generic substitutes. Patients may find that these restrictions reduce the quality of care they are receiving, and may feel that these restrictions reduce access at the expense of care.

CHAPTER 7

DESIGN OF AN OPTIMAL DRUG PAYMENT POLICY

A framework for examining the impact of federal drug payment policies on the various aspects of the pharmaceutical market has been developed in this study. The model offers the following advantages over the existing literature:

- it allows us to examine the impact of policies in the short run and the long run
- it focuses on the actions of different participants in the pharmaceutical industry, including payers, providers, patients, and government
- by using the multi-product firm model, it allows for simultaneous analysis of impacts on the different types of products within a manufacturer's portfolio
- it examines the different impacts of policies on the retail and institutional classes of trade
- it can isolate impacts of policies between the innovative and generic drug industries
- it can be used to examine the impact of federal drug payment policies on the prescription drug distribution network
- it allows us to examine the impact of drug payment policies on R&D decisions by drug manufacturers, both in terms of what drugs should be developed and on manufacturers' ability to earn sufficient returns to engage in R&D

In addition, analyses of impacts of specific government interventions in the pharmaceutical market have been examined in this report. Most of the approaches examined reflect incremental changes in the health financing system--specifically, revisions in the Medicare and Medicaid systems--rather than comprehensive health care reform. However, the applicability of the model is not limited to the policy options that were examined. Rather, the model can be also applied to more comprehensive reforms, such as the universal coverage proposals that were considered in the 103d Congress. Reflecting these issues, the study also includes analyses of the impact of direct drug price controls, the establishment of a drug price review board, and the implementation of unitary pricing laws.

Our analyses illustrate the difficulty of designing a policy that promotes all the several goals of an optimal federal prescription drug payment policy. As was discussed in earlier chapters, the government should be concerned with several aspects of the pharmaceutical market. These aspects include, of course, the ability of citizens to afford

required prescription drugs and the cost of any government programs or subsidies that are designed to increase consumer access. However, the government has also voiced a preference that its policy not inhibit the continuation of a strong pharmaceutical industry--currently the world's leader in new drug development--which provides substantial employment, export earnings, and development of new products that will improve the quality of life and perhaps reduce long-run health care costs. The government also may want to preserve competitive forces that, by themselves, can bring down drug costs while providing incentives for continued drug development.

One of the first conclusions that can be drawn from this study is that policies which focus primarily on increasing short-term access to prescription drugs do so at the cost to other public policy goals. One of these policies, direct price controls that bring low prices, can indeed significantly reduce the costs of obtaining prescription drugs to both consumers and payers. However, tightly applied price controls would adversely affect competitive forces in the pharmaceutical industry, prevent payers such as MCOs and PBMs from reaping rewards for finding more efficient ways to provide prescription drugs; and can distort incentives for drug development away from innovative products and towards imitative drugs. In addition, price controls may reduce the price of particular drugs, but by not recognizing the *economic price* of the products, they are inhibiting cost-effectiveness in medical treatment. The controls do not contain incentives for the appropriate use of drugs relative to one another, nor for the appropriate use of drugs relative to other medical treatments.

Similarly, the creation of a Medicare drug benefit without cost controls increases access to drugs for the over-65 population. But if the approach lacks incentives for the cost-reducing and cost-effective use of pharmaceuticals, then it likely will lead to a costly drug benefit and the potential of large welfare losses for society.

A second lesson from the analysis is that manufacturer drug rebates for public programs, used to bring prices paid by federal drug benefit programs closer to those paid by large institutional buyers, can actually shift costs to payers in the private sector and to all consumers (including beneficiaries). Both the Medicaid rebate and last year's proposed Medicare rebate are based on differences in price between the retail and institutional classes of trade. Manufacturers can reduce the size of the rebate by raising the price charged to the institutional class of trade, thereby decreasing the ability of institutional third-party payers to reap the rewards of their market power. In addition, since manufacturers would be expected to reduce the net impact of the rebate by raising all prices, the rebate can indirectly increase the payments made by all private payers. If the benefit includes cost sharing, then the impact of higher prices will also be felt by the beneficiaries to whom the programs directed.

The third lesson to be drawn from the analysis is that policies that are intended to increase consumer and physician sensitivity to prices can sometimes reduce consumer access to prescription drugs. The use of deductibles, copayments, and coinsurance decrease the welfare loss associated with economically inefficient levels of drug utilization,

but, to differing extents, can reduce affordability (particularly for low income households). In addition, the incentives for efficient drug utilization associated with deductibles and copayments do not always lead to such behavior. Policies aimed at lowering the cost of physician prescriptions, such as physician benchmarking and physician drug budgets, have the potential to reduce consumer access to more effective but more costly drugs. However, there is no hard evidence on the extent to which this reduced access would occur.

The fourth lesson from the analysis is that most of the cost control components of the policies discussed will have an adverse effect of drug manufacturer revenues and, presumably, the funds available for pharmaceutical R&D. Some of the approaches will affect all R&D, while others may have a greater influence on the incentives for developing major therapeutic improvements as opposed to imitative medicines. While the direction of these impacts is clear, however, the magnitude is not. It is not even clear which policies will have a nontrivial affect on drug manufacturer R&D decisions. Such analysis requires further study.

Finally, most of the approaches discussed in this study place a greater emphasis on drug cost than on drug cost-effectiveness. With one exception, the payment policy options we examined focus on prescription drug costs in isolation of the costs of other types of health services. Yet prescription drugs are used in conjunction with physician services, hospital care, as well as other components of health services. Their effective use may lead to cost reductions in these other areas, as well as in better value or improved outcomes for patients. The absence of consideration of cost-effectiveness may imply cost savings for prescription drugs that lead to overall health cost increases or less effective medical care.

The one example in our analysis that allows consideration of cost-effectiveness of drugs is the use of managed pharmacy benefits. Because managed care organizations receive a capitated payment for the provision and financing of a wide range of health care services--often including prescription drugs--they have a financial incentive to develop cost-effective ways for providing that care. Managed care organizations also have additional advantages over types of reimbursement policies. They often have policies in place to promote cost sensitivity by physicians and patients, they promote price competition by manufacturers, and they can develop innovative purchasing arrangements with manufacturers that can add value to both the payer and the manufacturer of drugs. However, the restrictions that these organizations sometimes place on product availability can be seen as restricting access to drugs by patients and physicians. Whether this lack of access affects the quality of medical care provided has yet to be determined.

The analysis thus suggest that an optimal policy must reflect the relative weights that society puts on each of these components. When society puts the greatest emphasis on low drug costs, it incurs the cost of market inefficiency and less drug development in the long run. When society emphasizes the need of drug manufacturers to earn high returns in order to finance product development, it does so at the cost of higher drug

prices and reduced access to prescription drugs. An emphasis by society on market efficiency and cost-effectiveness through the increased use of managed care in the pharmaceutical sector can result in innovative, competitive approaches between payers and providers, but could restrict choices of drugs available to consumers and physicians. By contrast, if society wants people to have access to prescription drugs no matter the cost, it runs the risk of fiscal pressures of running a drug benefit program in which prices and utilization are unrestricted. The resolution of these issues should be made in the political arena rather than in the writings of policy analysts. The best that can be done in the analytical arena is to give policy makers the best possible information about the impacts of the options they consider.

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